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A DESCRIPTIVE STUDY OF THE PERCENTAGE OF OXYGEN DELIVERED
USING THE MERCURY® TUBE-VALVE-MASK BREATHING CIRCUIT AT
2 L/MIN, 3 L/MIN, AND 4 L/MIN FLOW RATES

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A Cluster Research Study

submitted in partial fulfillment

of the requirements for the degree of

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School of Nursing

December, 2002

Abstract

The purpose of this study was to determine the efficacy of the Mercury® tube-valve-mask oxygen delivery system at 2 L/min, 3 L/min and 4 L/min flows using an oxygen concentrator (Oxygen 93% USP) and Oxygen 99% USP. A descriptive design was used. Eighteen healthy volunteers (ages 28-43) were recruited from the students and faculty at the Army Medical Department Center and School in San Antonio, Texas. The trials consisted of the subject breathing through the Mercury® tube-valve-mask breathing circuit at 2 L/min, 3 L/min and 4 L/min flow rates using an oxygen concentrator (Oxygen 93% USP) and Oxygen 99% USP. Each subject was randomly assigned to order of oxygen source and flow rate, received all 6 trials, and served as their own control. The subject breathed from the oxygen source and flow rate selected until a sustained fraction inspired oxygen concentration (FiO_2) was determined. Once the sustained FiO_2 was determined and there was less than a 10% variation in FiO_2 , a three-minute trial began. Data collection consisted of the subjects FiO_2 , respiratory rate, tidal volume and minute volume. It was hypothesized that the Mercury® tube-valve-mask breathing circuit would deliver a FiO_2 of 0.40, 0.50, and 0.60 at flow rates of 2L/min, 3L/min, and 4L/min, respectively. A Chi-square goodness-of-fit test was used to determine if 85% of the subjects achieved the desired FiO_2 at the predetermined flow rate. The 85 % criterion was not reached in any of the conditions tested. The mean FiO_2 at 2L/min was 0.35 with Oxygen 93% USP and 0.36 with Oxygen 99% USP. The mean FiO_2 at 3 L/min was 0.45 with Oxygen 93% USP and 0.45 with Oxygen 99% USP. The mean FiO_2 at 4 L/min was 0.52 with Oxygen 93% USP and 0.53 with Oxygen 99% USP. Although the predicted values of FiO_2 were not met, it was found that the Mercury® tube-valve-mask breathing

circuit was capable of delivering higher concentrations of oxygen than traditional oxygen delivery systems. Currently, the Mercury[®] tube-valve-mask breathing circuit is the only oxygen delivery system available that can deliver high concentrations of oxygen at these low flow rates.

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NOTICE OF APPROVAL TO BEGIN RESEARCH

June 1, 2001

HSC-SN-01-008 - "A Descriptive Study of the Percentage of Oxygen Delivered using the Mercury® Tube-Valve-Mask Breathing Circuit at 2 L/min, 3 L/min, and 4 L/min Flow Rates"

PI: Brent Mitchell, MSN Student; et al

PROVISIONS: Unless otherwise noted, this approval relates to the research to be conducted under the above referenced title and/or to any associated materials considered at this meeting, e.g. study documents, informed consents, etc.

APPROVED: At a Convened Meeting

APPROVAL DATE: May 18, 2001

EXPIRATION DATE:

April 30, 2002

CHAIRPERSON: Anne Dougherty, MD

Subject to any provisions noted above, you may now begin this research.

CHANGES - The P.I. must receive approval from the CPHS before initiating any changes, including those required by the sponsor, which would affect human subjects, e.g. changes in methods or procedures, numbers or kinds of human subjects, or revisions to the informed consent document or procedures. The addition of co-investigators must also receive approval from the CPHS. **ALL PROTOCOL REVISIONS MUST BE SUBMITTED TO THE SPONSOR OF THE RESEARCH.**

INFORMED CONSENT - Informed consent must be obtained by the P.I. or designee using the format and procedures approved by the CPHS. The P.I. must instruct the designee in the methods approved by the CPHS for the consent process. The individual obtaining informed consent must also sign the consent document.

UNANTICIPATED RISK OR HARM, OR ADVERSE DRUG REACTIONS - The P.I. will immediately inform the CPHS of any unanticipated problems involving risks to subjects or others, of any serious harm to subjects, and of any adverse drug reactions.

RECORDS - The P.I. will maintain adequate records, including signed consent documents if required, in a manner which ensures confidentiality.

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CHAPTER I

Introduction

Joseph Priestley discovered oxygen in 1774, and its use as a therapeutic drug was first documented in 1783. Today, oxygen is the most frequently administered drug in the hospital setting (Martin, 1999). One of the most common delivery methods is by nasal cannula, which provides low flow oxygen at concentrations up to 44%. Oxygen can also be delivered by a mask when it is necessary to achieve higher oxygen concentrations. Unfortunately, to achieve higher oxygen concentrations, oxygen flows of 6-15 liters per minute (L/min) via a non-rebreathing mask are necessary (Shapiro & Peruzzi, 2000). The use of high flow delivery systems are typically not a problem in hospital environments supplied by high-pressure pipeline gas. However, when using oxygen cylinders these delivery systems are neither an economical nor an efficient choice.

Most oxygen delivered in hospitals is supplied from medical gas pipeline systems that rely on liquid oxygen. Smaller facilities and mobile medical units require large gas cylinders for oxygen storage and delivery (Dorsch & Dorsch, 1999). The oxygen concentrator was developed to provide an alternate source of oxygen without the logistical problems and economic concerns of pipeline and cylinder oxygen. Oxygen concentrators that can concentrate the oxygen from room air have become popular for home use and are also being used in medical facilities. In 1987, hospitals in the province of Manitoba, Canada began using oxygen concentrators as the primary supply of hospital oxygen. A study of these hospitals found the oxygen concentrators to provide a safe, reliable and cost effective supply of oxygen (Friesen, Raber, & Reimer, 1999).

Statement of the Problem

The oxygen concentrator could prove to be beneficial to military medical practice in the field environment. The current delivery of oxygen to the field consists of large gas cylinders and liquid oxygen. The delivery of gas cylinders and liquid oxygen to remote locations is often a difficult task. Oxygen concentrators can reduce or eliminate the need for oxygen cylinders in the field. The Mercury[®] tube-valve-mask breathing circuit is designed to administer high concentrations of oxygen at low flow rates. The use of oxygen concentrators with the Mercury[®] tube-valve-mask breathing circuit will reduce the cost and the logistical problems associated with oxygen supply in the field environment. This study determined the efficacy of the Mercury[®] tube-valve-mask breathing circuit when delivering oxygen at 2 L/min, 3 L/min and 4 L/min flow rates using an oxygen concentrator [Oxygen 93% United States Pharmacopoeia (USP)] or oxygen supplied from a medical gas company (Oxygen 99% USP).

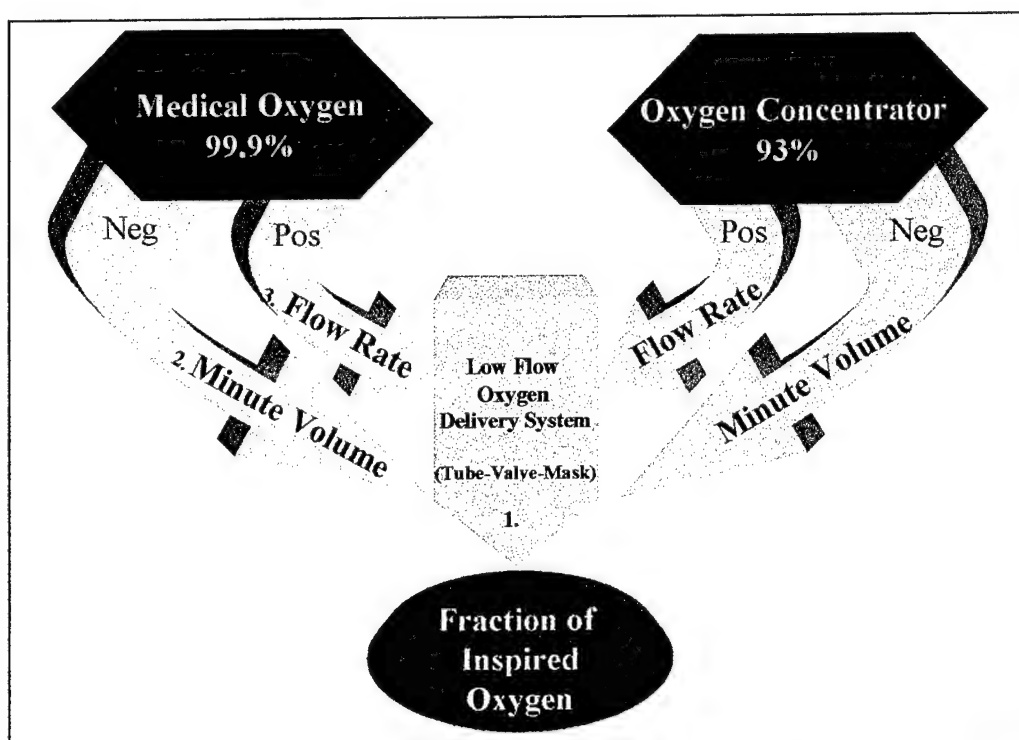
Significance of the Problem

The traditional hospital source of oxygen is supplied from pipeline liquid oxygen systems. Smaller facilities and mobile medical units require large gas cylinders for oxygen storage and delivery. Oxygen concentrators that concentrate oxygen from ambient air can provide an alternate source of oxygen. Oxygen concentrators have been found to provide a safe, reliable and cost effective supply of oxygen (Friesen et al., 1999). Several oxygen delivery devices are currently used in medical treatment facilities. Most of these devices require high flows of oxygen to deliver a high oxygen concentration to the patient. The Mercury[®] tube-valve-mask breathing circuit was developed to replace these high flow systems. The combination of the Mercury[®] tube-

valve-mask breathing circuit with the oxygen concentrator will provide a cost effective, logistically sound alternative to the current systems in use today.

Theoretical Framework

According to Mackie (1987), the major determinants of the fraction of inspired oxygen (F_{iO_2}) are total ventilation, oxygen flow and reservoir size. The fraction of inspired oxygen available through an oxygen delivery system is based on Dalton's Law of partial pressure. The conceptual framework (see Figure 1) for this study was based on this law, which states total pressure is equal to one atmospheric pressure or 763 millimeters of mercury (mmHg). Air is a mixture of gases including nitrogen, oxygen, carbon dioxide, argon and other trace gases. The partial pressure that each gas exerts in the mixture is proportional to its concentration in the air. The partial pressure of a gas is a direct function of its atmospheric concentration. The total pressure of a mixture of gases is equal to the sum of the partial pressures of each of the gases (see Figure 2). In atmospheric air, the concentration of oxygen is about 21% with a partial pressure of 149 mmHg. The concentration of nitrogen is 79% with a partial pressure of 563 mmHg. The concentration of carbon dioxide is 0.03% with a partial pressure less than 1 mmHg. The total pressure of dry gases is equal to the barometric pressure minus the water vapor pressure (763 mmHg - 47 mmHg) or 713 mmHg. As the partial pressure of one gas is increased, the partial pressure of the other gases will be reduced proportionally to ensure the total partial pressure of the gases available does not exceed that of the barometric pressure (Berne & Levy, 1988).



1.
Tube-Valve-Mask
-Tube: 42 inch coaxial reservoir
-Valve: Non-rebreathing fishmouth
-Mask: Anesthesia mask
2.
Minute Volume (V_e)
- V_e = respiratory rate x tidal volume
3.
Flow Rate
-The amount of gas delivered from the concentrator in liters per minute.

Figure 1. Conceptual Framework*

Note.* F_iO_2 varies directly with the flow rate and indirectly with the minute volume when oxygen is delivered by either an oxygen concentrator (93% USP) or Medical Oxygen (99% USP) through the tube-valve-mask system.

$$P_T = P_1 + P_2 + P_3 + P_4$$

P_T = the total pressure of a gas (atmospheric pressure)

P_1 = partial pressure of oxygen

P_2 = partial pressure of nitrogen

P_3 = partial pressure of carbon dioxide

P_4 = water vapor pressure

Figure 2. Formula for Dalton's Law of Partial Pressure

The volume of gas that is inspired or expired in a unit of time can be measured as ventilation. The product of tidal volume and the breathing frequency is equal to minute ventilation. Minute ventilation and oxygen consumption are closely related. As oxygen consumption increases, minute ventilation will increase to provide for greater availability of oxygen for the tissues (Berne and Levy, 1988). Clinically, there are significant physiologic variables affecting oxygen consumption regardless of the delivery system used. Figure 3 illustrates the formula for oxygen consumption (VO_2). Oxygen consumption is the amount of oxygen consumed per kilogram of body weight per minute (Levitzky, 1999). The VO_2 in a normal eight-year-old child is 4.9 ml/kg/min. The expected adult VO_2 is 3.4 ml/kg/min. During normal daily living, people expend energy whether they are sleeping or exercising. Energy expenditure occurs at varying rates in different individuals based on body type, activity level and gender. Several factors are known to affect oxygen consumption to include basal metabolic rate (BMR), gas exchange and body mass index (BMI) (Guyton, 2000).

$$V_{O_2} = Q_t \times (C_{aO_2} - C_{vO_2})$$

V_{O_2} = the total amount of oxygen absorbed by the body per minute

Q_t = the cardiac output in ml/min

C_{aO_2} = the arterial oxygen content in 100ml of blood

C_{vO_2} = the mixed venous oxygen content in 100 ml of blood

Figure 3. Oxygen consumption

Basal metabolic rate (BMR) is defined as the minimum level of energy required to survive. Skeletal muscle accounts for 20% to 30% of the normal BMR (Guyton, 2000). Depending on the amount of skeletal muscle and physical activity, BMR can be highly variable between individuals. In an average 70 kilogram male, normal BMR expends about 65 to 70 calories per hour. BMR accounts for 60% of the daily energy expenditure, while the thermic effect of food, non-exercise activity and purposeful physical activity account for the remaining 40% (Guyton, 2000).

However, energy expenditure cannot occur without adequate gas exchange and oxygen consumption. Gas exchange is the diffusion of oxygen from the alveoli into the pulmonary circulation and the diffusion of carbon dioxide from the pulmonary circulation into the lungs to be exhaled (Guyton, 2000). Diffusion of gases is the movement of molecules from an area of higher partial pressure to an area of lower partial pressure. The principle function of the lung is to maintain adequate distribution of inhaled oxygen and pulmonary blood flow for the appropriate exchange of oxygen and carbon dioxide (Berne & Levy, 2000). For gas exchange to occur, ventilation must take place. Ventilation is defined as the frequency of breathing multiplied by the tidal volume (the volume of each breath). Adequate ventilation maintains the normal oxygen and carbon dioxide concentrations in the alveoli, as well as the appropriate partial pressures for the gases to diffuse (Berne & Levy, 2000).

Body mass index has also been shown to alter gas exchange. BMI is calculated by dividing the weight in kilograms by the height in meters squared. A normal BMI is less than 25. A BMI of 25 to 27 has been shown to increase the likelihood of diabetes, hypertension and cardiovascular disease (Berne & Levy, 2000). In a study done by

Pelosi et al. (1998), as BMI increased, functional residual capacity (FRC) decreased exponentially with patients in the supine position undergoing general anesthesia. Levitzky (1999) defines FRC as the volume of gas in the lungs at the end of a normal tidal expiration when no respiratory muscles are actively contracting. In the supine position, a reduction in lung volume occurs and limits the amount of oxygen available for exchange. When supine, the abdominal contents push against a relaxed diaphragm causing a cephalad displacement of the diaphragm, resulting in a decreased lung volume. As shown by Pelosi et al. (1998), a large BMI further decreases lung volume. This study also demonstrated several other significant findings related to BMI with patients in the supine position. It was found that as BMI increased, the resistance of the total respiratory system and the work of breathing of the respiratory system increased. In addition, the oxygenation index, defined as the partial pressure of arterial oxygen divided by the partial pressure of alveolar oxygen (PaO_2/PAO_2), decreased exponentially correlating with the decreased FRC in the supine position.

Factors known to increase VO_2 include pregnancy, excessive sympathetic stimulation, hyperthermia, shivering and excessive thyroid hormone (Guyton, 2000). In pregnancy, an additional 20% decrease in FRC occurs at term due to an upward displacement of the diaphragm. Pregnancy also increases oxygen uptake by 20% due to increased maternal metabolism and work of breathing. Minute ventilation is increased at term by about 50% due to an increase in tidal volume (Shnider & Levinson, 1994). Excessive sympathetic stimulation also increases VO_2 . Sympathetic stimulation increases blood flow to active muscles, cellular metabolism, glycolysis, muscle strength and respiratory rate (Guyton, 2000). Oxygen consumption during normal quiet breathing

is normally less than 5% of the total body oxygen uptake. This oxygen consumption can increase drastically as the work of breathing increases (Levitzky, 1999).

Obesity also has an affect on VO_2 during normal quiet breathing. In the study done by Kress, Pohlman, Alverdy, & Hall (1999), morbid obesity ($BMI > 40$) was associated with a considerable increase in VO_2 during quiet breathing when compared with normal control patients. Shivering increases oxygen consumption nearly 100% (Sessler, 1994). Excessive thyroid hormone increases the metabolism in almost all cells including the heart where it acts to increase heart rate and contractility, which increases the oxygen consumption (Guyton, 2000). In addition, excessive thyroid hormone can increase resting oxygen consumption from 250 ml/min to nearly 400 ml/min. Excessive thyroid hormone also increases the resting ventilatory rate to sufficiently maintain normal oxygen pressures. Therefore, increased BMR elevates the total oxygen consumption (Berne & Levy, 2000).

Increasing the concentration of oxygen available for inspiration can occur through several different modalities. Low flow oxygen therapy can be defined as flow rates of less than 10 L/min (Burton, Hodgkin, & Ward, 1997). Low flow equipment delivers oxygen at a fixed rate of flow that is less than the total volume of inspired gas. These systems entrain a variable amount of room air based on changes in the ventilatory demand of an individual. High gas flows are considered greater than 10 L/min. High flow devices deliver all inspired gas at a preset FiO_2 without entrainment of room air. Variations in breathing patterns or ventilatory demands generally do not affect the FiO_2 when used in high flow devices. As you increase the flow rate, you will increase the FiO_2 that is delivered through the system (Burton et al., 1997).

The addition of a reservoir to an oxygen delivery system increases the amount of oxygen available during inspiration. The reservoir provides a means to collect oxygen when the inspiratory valve is closed during expiration (Dorsch & Dorsch, 1999). When the inspiratory valve from the oxygen delivery device opens, oxygen from the reservoir enters the mask. The size of the reservoir may limit the oxygen concentration delivered. If the volume of the reservoir is less than the inhaled tidal volume, the inflowing oxygen will be diluted by air drawn into the reservoir by the patient's negative inspiratory force (Dorsch & Dorsch, 1999).

The amount of oxygen available in the reservoir for inspiration directly affects the amount of oxygen that is available for diffusion in the alveoli. According to Fick's law of diffusion, the exchange rate of oxygen and carbon dioxide is inversely proportional to the thickness of the membrane. Fick's law also shows that the rate of diffusion is directly proportional to the area of the membrane available, the diffusion coefficient of the gas and the partial pressure difference across the membrane. An increase in the FiO_2 results in an increased partial pressure difference of oxygen across the alveolar membrane. The thickness of the alveolar membrane is about 0.2 to 0.5 micrometers (Levitzky, 1999). Factors such as interstitial edema and pulmonary fibrosis increase the thickness of the alveolar membrane significantly increasing diffusion time (Guyton, 2000). The surface area of the barrier between the blood and gas in the alveoli is approximately 70 meters squared. The surface area of the alveolar membrane is known to decrease during times of decreased venous return. The diffusion coefficient is directly proportional to the solubility of the diffusing gas and inversely proportional to the square root of the molecular weight of the gas. Based on the diffusion coefficient, carbon

dioxide diffuses about 20 times faster than oxygen (Levitzky, 1999). The partial pressure difference is the difference between the partial pressures in the alveoli and the pulmonary blood. For oxygen to diffuse from the alveoli into the blood, the partial pressure of oxygen must be higher in the alveoli. For carbon dioxide to diffuse from the blood into the alveoli, the partial pressure of carbon dioxide must be higher in the blood (Levitzky, 1999). These physical laws define the factors affecting gas exchange.

Purpose

The purpose of this study was to determine the efficacy of the Mercury[®] tube-valve-mask breathing circuit when delivering oxygen at 2 L/min, 3 L/min and 4 L/min flows using an oxygen concentrator (Oxygen 93% USP).

Definition of Terms

FiO₂. Conceptual definition: The fraction of oxygen in the inspired gas (Levitzky, 1999). Operational definition: The fraction of oxygen in the inspired gas as measured by the Ohmeda[®] Respiratory Gas Monitor (RGM).

Flow rate. Conceptual definition: The volume of gas passing a specific point per unit of time (Dorsch and Dorsch, 1999). Operational definition: 2 L/min, 3 L/min and 4 L/min flow rates as measured by the Litton[®] Life Support flowmeter with oxygen from the oxygen concentrator or Oxygen 99% USP.

Mercury[®] tube-valve-mask breathing circuit. Conceptual definition: A modified Mapelson F anesthesia circuit with a non-rebreathing fishmouth valve (Dorsch & Dorsch, 1984). Operational definition: A semi-open breathing circuit composed of a non-rebreathing valve-mask assembly attached to a coaxial delivery system consisting of corrugated tubing providing a reservoir of oxygen for patient delivery.

Minute Ventilation. Conceptual definition: The volume of air entering or leaving the nose or mouth per minute. It is calculated by the respiratory rate multiplied by tidal volume (Levitzky, 1999). Operational definition: Minute ventilation will be determined on expiration using the Ohmeda® RGM gas analyzer.

Molecular sieve oxygen concentrator. Conceptual definition: A device that uses a molecular zeolite sieve to separate oxygen from ambient air in order to provide an oxygen enriched gas source (Friesen, 1992). Operational definition: The AirSep® New Life Oxygen Concentrator will provide the concentrated oxygen.

Oxygen. Conceptual/Operational definition: The United States Pharmacopoeia defines oxygen as percent oxygen by volume. Hospital pipeline oxygen is defined as Oxygen 99% USP, and is obtained by cryogenic liquefaction. Oxygen 93% USP is defined as oxygen obtained from an oxygen concentrator using molecular sieve technology (Eckenhoff & Longnecker, 1996).

Hypotheses

Research Hypothesis #1: The Mercury® tube-valve-mask breathing circuit will deliver a fractional inspired oxygen concentration of 0.40 when supplied with concentrator gas (Oxygen 93% USP) or Oxygen 99% USP at 2 L/min.

Research Hypothesis #2: The Mercury® tube-valve-mask breathing circuit will deliver a fractional inspired oxygen concentration of 0.50 when supplied with concentrator gas (Oxygen 93% USP) or Oxygen 99% USP at 3 L/min.

Research Hypothesis #3: The Mercury® tube-valve-mask breathing circuit will deliver a fractional inspired oxygen concentration of 0.60 when supplied with concentrator gas (Oxygen 93% USP) or Oxygen 99% USP at 4 L/min.

Assumptions

1. The healthy subject provided a current and accurate health history.
2. The physiologic characteristics of the sample under study were normally distributed.
3. The subject breathed a normal minute ventilation based on the calculated value for tidal volume.
4. There was no accumulation of inert gases.
5. The percent of oxygen concentration supplied from the concentrator was consistent within described parameters.
6. An adequate mask seal was obtained on all subjects.
7. The valve functioned appropriately.

Limitations

1. Potential for attrition due to subject's request or investigators' termination of the trial.
2. We were looking at a healthy population at a resting state. We were not looking at subjects with altered oxygen consumption states, so we were not able to generalize to any population other than a healthy one.
3. We used a convenience sample, which limited the ability to generalize findings.

CHAPTER II

Review of the Related Literature

The purpose of this literature review was to examine the research as it related to current mask oxygen delivery systems, non-rebreathing valves in oxygen delivery devices and oxygen concentrators as an alternative oxygen supply. The information from this literature review provided the foundation for research into the use of the Mercury[®] tube-valve-mask breathing circuit to supply oxygen by an oxygen concentrator as a low flow oxygen delivery device on healthy subjects.

Mask Oxygen Delivery Systems

Current oxygen delivery systems in use for preoperative and postoperative anesthesia care in the military include the simple facemask, venturi mask, non-rebreathing mask, Ambu bag and Jackson-Rees resuscitation bag. All of these systems require high flows of oxygen in order to prevent rebreathing of exhaled gases. The simple facemask is a plastic mask that fits over the nose and mouth. The oxygen source enters the mask at the base, and two holes are in the mask to provide a route for exhaled gases to escape. On inspiration, the patient inhales oxygen and room air. On expiration, exhaled gases and oxygen escape. The simple facemask provides humidified oxygen concentrations of 30-50% with oxygen flow rates of 6-12 L/min (Temper & Lewis, 1987). The venturi mask is a modified version of the simple facemask and can provide higher and more exact concentrations of oxygen. Adapters are applied to increase humidification and oxygen concentrations. Flow rates must remain between 6-12 L/min in order to entrain the requisite volume of room air necessary to accurately dilute the oxygen to the desired concentration.

A non-rebreathing mask is a simple facemask with a reservoir bag attached. Oxygen flows into the bag and mask continuously. A valve is present on the bag to prevent expired air from returning and diluting the oxygen in the reservoir bag. A pair of discs located on the facemask facilitates one-way flow of expired gases into the atmosphere. Oxygen concentrations of 60-90% can be reliably delivered with this system. The partial non-rebreathing system is similar to the non-rebreathing system but is only able to deliver a maximum of 60% oxygen. This system does not have the valves on the mask or the reservoir bag and allows for conservation of the first one-third of the patient's breath (Temper & Lewis, 1987).

The Ambu bag or manual resuscitation bag consists of a compressible self-inflating bag, a valve that assists in the filling of the bag and a valve that prevents rebreathing of gases. Oxygen is delivered near the bag refill valve or in some cases directly into the bag to increase the concentration of oxygen delivered to the patient. Some bags have a corrugated tubing reservoir attached. The oxygen flows into the reservoir when the bag is not filling. If the volume of the tubing is less than the volume of the bag, then room air can be entrained and will result in a decreased oxygen concentration delivered. The oxygen flows that are required for the manual resuscitators are 10-15 L/min (Dorsch & Dorsch, 1999). Several different sizes of reservoirs are commercially available. A study done by Barnes and Watson (1983) demonstrated that in order to achieve high oxygen concentrations consistently, flows greater than 10 L/min are required. This study also showed that at a flow rate of 5 L/min, the FiO_2 did not exceed 0.70 regardless of the size of the reservoir.

The Jackson-Rees circuit, also known as a modified Mapleson F circuit, consists of corrugated tubing, an oxygen source port and a reservoir bag with an adjustable valve at the distal end of the bag. The system can be used for both spontaneously breathing patients and those requiring assisted or controlled ventilation. As the patient exhales, gases accumulating in the tubing and the reservoir bag escape from the valve at the distal end of the bag. With high gas flows, the reservoir bag fills with oxygen that the patient then breathes upon inspiration. High oxygen flow, low tidal volume and a long expiratory time help to minimize the amount of rebreathing that occurs with this system. The minimum fresh gas flow that is required to prevent rebreathing is 5 L/min (Dosch, 2000).

Further refinement of these systems led to the development of the Mercury[®] tube-valve-mask breathing circuit that we studied. The Mercury[®] tube-valve-mask breathing circuit was developed to replace current oxygen delivery systems in use today in deployment situations and in fixed facilities in the military. The Mercury[®] tube-valve-mask breathing circuit is a semi-open oxygen delivery system consisting of a fishmouth valve and a corrugated tubing reservoir that is 42 inches long with a volume of 468 ml. Mackie (1987) found that at a 1 L/min flow, the volume of the reservoir was not a determining factor in the FiO_2 delivered to the patient by a semi-open circuit. However, at a flow rate of 4 L/min, the large reservoir delivered a significantly higher fraction of inspired oxygen than the small reservoir. Mackie (1987) calculated that a reservoir volume of 415 ml is needed to deliver a FiO_2 of 0.90 at 4 L/min. The valve is located proximal to the patient and permits unidirectional flow of oxygen from the source to the patient without rebreathing exhaled gases. An oxygen tube is threaded through the

corrugated housing. This coaxial arrangement serves to preserve heat and humidity within the respiratory circuit and is designed for continuous oxygen delivery.

As oxygen is delivered distal to the non-rebreathing valve it collects in the tubing until the patient inhales. The expiratory flap provides a means for exhaled gases to escape. (e.g. J. Schretenthaler, personal communication, January 18, 2001). As the patient inhales, the non-rebreathing valve opens, causing closure of the expiratory flap, allowing for the concentration of oxygen that has accumulated in the reservoir to be inspired by the patient. Because the expiratory flap closes the circuit to the atmosphere, room air is not entrained in the facemask with inspiration, thus the concentration of oxygen is not diluted. As the patient exhales, the non-rebreathing valve closes, and the expiratory flap opens. This action prevents the build up of CO₂ in the facemask and prevents exhaled gases from escaping into the corrugated tubing, thus no rebreathing occurs. The addition of this unidirectional valve to the oxygen delivery circuit allows us to minimize the flow required for adequate oxygenation. In addition, this valve prevents rebreathing of exhaled gases (Sykes, 1958).

Mercury Non-Rebreathing Valve

The valve used in the Mercury[®] tube-valve-mask breathing circuit is a reproduction of the Laerdal[®] Mark IV anesthesia valve. It is classified as a non-rebreathing fishmouth valve that can be used for spontaneous or controlled ventilation. The term "fishmouth" refers to the design of the valve, which resembles a fish's mouth. It is a special type of flap valve in which two flaps approximate at a midpoint when closed. This occurs during expiration. The Mark IV valve has been widely used for many years with resuscitation devices in hospitals and for critical transports (Ho,

Sharagge, Tittley, Fedoryshyn, Purksa, 1996). The only difference between the original Laerdal® valve and the newer version produced by Mercury® Medical is the addition of an inspiratory/expiratory gas monitoring port having no impact on the functionality of the valve. When the patient inhales, the fishmouth valve opens causing the expiratory disc to seat against the exhalation port. Fresh gas flows to the patient, but atmospheric air is prevented from entering the system. When the patient exhales, the expiratory flap is lifted open by closure of the fishmouth valve. Exhaled gas is released to the atmosphere through the exhalation ports in the valve housing preventing the ingress of air to the patient and the return of alveolar gases to the circuit (Dorsch & Dorsch, 1984).

For the spontaneously breathing patient, it is important to keep a low resistance to flow throughout the system. The Mercury® expiratory disc is a lightweight circular disc constructed of rubber. The flap is not attached so the patient only lifts the weight of the rubber disc. Patients expend minimal effort to lift (open) the disc due to its light weight and high efficiency. When the patient inhales, the disc simply falls back into a seated position as fresh gas is forced through the fishmouth valve. Stephen and Slater (1948) demonstrated that at a flow rate of 4.7 L/min, the valve exerts only 0.32 centimeters in water of resistance on inspiration. On expiration the valve exerts only 0.16 centimeters in water of resistance. Non-rebreathing flap valves have been used on infants three to five weeks old for up to two hours without any evidence of fatigue (Stephen & Slater, 1948).

The reliability and durability of this valve is an important consideration. Even though the proposed system is intended to be used by the Army as a disposable unit, the Mercury® valve is constructed and has been used since its inception as a non-disposable component (Ho, et al, 1996). Despite this fact, incidents of malfunction following

disassembly for cleaning are rare. The only reported problems associated with this valve design were caused by the assembler inadvertently placing two disks together during reassembly after sterilization (Ho, et al, 1996). In the Mercury® Medical version of the Mark IV, the manufacturer places the valve in the tube-valve-mask assembly and the entire unit is discarded after a single use.

The Mercury® valves' mechanical soundness is a direct result of its simplicity. As with other non-rebreathing valves, this molded rubber disc design has no chemical reaction with the inhaled gases. Likewise, the efficiency of the valve is not impaired by moisture collecting on the rubber disc (Stephen & Slater, 1948). The care and cleaning instructions of the original Mark IV (disassembling, boiling, autoclaving and using chemical solutions) are themselves a testament to this valve's durability (Dolan, Shapiro & Stienbach, 1981). Regardless of its efficacy and safety, a valve is only of sound clinical use when attached to a reliable oxygen source.

Molecular Sieve Oxygen Concentrator

Oxygen concentrators are devices that are capable of filtering out oxygen from ambient air thereby providing an oxygen-enriched gas source. Since the goal is to decrease or eliminate mobile military medical units' reliance upon conventional cylinder based oxygen supply, an oxygen concentrator is a logical alternative. Molecular sieve, membrane and electrochemical technologies are three methods by which oxygen is concentrated (Eckenhoff & Longnecker, 1996). The molecular sieve process will be discussed, as it will be the method used in this research project.

Oxygen concentrators that use a molecular sieve process allow for the selective adsorption of the components of atmospheric air. The molecular sieve allows for oxygen

and argon to pass through while removing nitrogen. This is accomplished by using a synthetic zeolite sieve (Chusid, 1982). Zeolite is a naturally occurring substance that selectively adsorbs components of the air. Synthetic zeolite sieves are used because they provide for a more uniform consistency of the filter media. The synthetic zeolite consists of a framework of silica and aluminum with an added cation (calcium or sodium) to balance the charges in the structure. The molecular sieves are available as crystallized zeolite pellets (Friesen, 1992).

The oxygen concentrator is composed of a fresh air intake with a filter, an air compressor with air cooler and storage tank and the zeolite molecular sieve cylinders. The zeolite molecular sieve has numerous pores that have a net positive charge. It is the molecular size and polarity of the gases that are exposed to the zeolite that determine whether or not they will be adsorbed (Friesen, 1992). Selective adsorption of gases allows the oxygen concentrators to separate out the nitrogen from ambient air to produce a gas that has a high oxygen concentration.

Molecular sieve concentrators are able to supply a continuous output of oxygen by using a pressure swing adsorption cycle (PSA). The oxygen concentrator has two cylinders of packed zeolite crystals that operate in a synchronized adsorption-desorption cycle. During the PSA cycle, while one cylinder is adsorbing nitrogen under pressure the other cylinder is depressurized and the nitrogen is discharged to the environment as waste gas (Chusid, 1982). The zeolite column is then regenerated by application of a negative pressure at the end of each cycle or by flushing the column with a small amount of the just-generated oxygen (Friesen, 1992). In this manner, air is flowing through one cylinder while the other is regenerating. The result is a continuous supply of oxygen.

An evaluation of six oxygen concentrators by Johns, Rochford & Streeton (1985) found that the mean oxygen concentration produced by molecular sieve concentrators was between 94% and 95% at a flow of 2 L/min and varied by less than 0.5%. Another finding was that the percentage of oxygen obtained decreased as the flow rate increased. Gould, Scott, Hayhurst & Flenley (1985) and Harris and Simpson (1985) found similar results. In three of the four machines tested, Gould et al. (1985) found oxygen concentrations between 93.2% and 94.2% with a flow rate of 2 L/min. The fourth machine delivered only 88.3% oxygen concentration. Harris and Simpson (1985) reported oxygen concentration results of 90-93% at 2 L/min flow rate. Both studies also found that the concentration of oxygen delivered decreased as the flow rate increased.

The United States Pharmacopoeia defines oxygen by percent volume. Oxygen supplied by cryogenic liquefaction is defined as Oxygen 99% USP. The oxygen from molecular sieve concentrators is defined as Oxygen 93% USP by volume. The remainder of concentrator produced gas is mainly argon with trace amounts of nitrogen (Friesen, 1992). Since concentrator oxygen is only 93% by volume, concerns regarding naturally occurring argon enrichment must be addressed. A study by Parker and Snowdon (1988) addressed the accumulation of argon in anesthesia breathing circuits with low fresh gas flows from a molecular sieve oxygen concentrator. In this study end-tidal gas samples were analyzed for the percent concentrations of oxygen, argon and nitrogen in circle breathing systems at fresh gas flows ranging from 310 ml/min to 2 L/min. This study found that the end-tidal argon concentrations increased with time. The rate and extent of argon accumulation increased as the fresh gas flow was reduced. The percent of oxygen concentration decreased with time and again the decrease was greater as the fresh gas

flow was reduced. The percent concentration of nitrogen increased only when the circle system was fully closed.

The accumulation of argon in inspired gas appears to have no biological effect. Horrigan, Wells, Guest, Hart & Goodpasture (1979) studied eight human volunteers who were exposed to a gas mixture of 80% argon and 20% oxygen for 30 minutes. The investigators found no change in oxygen or carbon dioxide tensions in either muscle or subcutaneous tissues with this concentration of argon. There were also no significant changes in hematological studies found in the subjects after exposure to the argon-rich gas. According to Parker and Snowden (1988) the problem with the accumulation of argon appears to be displacement of oxygen in the inspired gas.

Concentrator oxygen is essentially a filtrate of ambient air. A concern of importance to the military is the potential for contamination of the oxygen concentrator supply. Libby, Briscoe, King & Smith (1979) found that in two oxygen concentrators studied, no toxic gases such as hydrocarbons, carbon monoxide or sulfur oxides were generated by the concentrators after 24 hours of continuous use. According to Friesen (1992), the zeolite molecular sieve can effectively filter out most contaminants in air including motor vehicle exhaust, jet aircraft exhaust, ethylene oxide and sulfur dioxide. The molecular sieve also effectively filters out chemical warfare agents such as mustard gas, sarin, hydrogen cyanide and cyanogen chloride as well as dimethyl methylphosphonate, methyl chloride and perfluoroisobutylene (Friesen, 1992).

Critique of the Literature

Oxygen delivery devices have been used for several years to deliver set amounts of oxygen using high flows. Many studies have been done using high flow oxygen with

these devices. Barnes and Watson (1983) found that in order to achieve a high FiO_2 consistently, a minimum of 10 L/min oxygen flows are required. Their study also showed that FiO_2 did not exceed 0.70 regardless of the reservoir size. Mackie (1987) used low flows in a drawover anesthesia system to demonstrate that at 4 L/min flow rates, a reservoir size of 415 ml is needed to maintain FiO_2 of 0.90. The reliability and validity of the results in both studies require verification due to the incomplete description of the methodology used in the studies.

Non-rebreathing valves have been in use for more than fifty years. These valves were developed as a means to deliver high flow oxygen concentrations with low resistance to infants and children (Stephen & Slater, 1948). Today, non-rebreathing valves are used for both spontaneous and controlled ventilation in a variety of settings, but not for low flow oxygen delivery (Dorsch & Dorsch, 1984). The available literature focused on describing the resistance offered by the different types of non-rebreathing valves at higher oxygen flow rates (>5 L/min), not on whether an adequate fraction of inspired oxygen can be achieved at flow rates < 5 L/min.

The safety and reliability of molecular sieve oxygen concentrators has been documented in the literature. Four studies (Libby et al, 1979; Gould et al, 1985; Harris & Simpson, 1985; Johns et al, 1985) have demonstrated that molecular sieve oxygen concentrators are capable of providing oxygen concentrations of $> 90\%$ at a flow rate of 2 L/min. These studies all measured the percent concentration of oxygen obtained directly from the oxygen concentrators themselves. Only Libby et al (1979) addressed the use of the oxygen concentrator with the delivery of oxygen via a mask (Venturi). They found that with the Venturi mask set for 24%, the oxygen concentrators were capable of

delivering 23.7% to 24.9%. With the Venturi mask set to deliver 28%, the concentrators delivered 28.2% to 28.6%. There is no study that addresses the use of a molecular sieve oxygen concentrator with a tube-valve-mask breathing circuit.

Parker and Snowden (1988) studied the use of a molecular sieve oxygen concentrator while delivering low flow and closed circuit anesthesia. Their study addressed the issue of argon accumulation in semi-closed and closed anesthesia breathing circuits. They found that over time the percent of argon accumulated in the breathing circuit and that the rate and extent of the increase was greater as the fresh gas flow was reduced. This increase in argon concentration was complimented by a decrease in the oxygen concentration at each fresh gas flow setting. Only when the breathing circuit was fully closed was the decrease in oxygen concentration greater than the increase in argon concentration. In this case, the decrease in oxygen concentration was due not only to the increase in argon concentration but also to the increase in nitrogen concentration. Parker and Snowdon (1988) concluded that when using a fully closed anesthesia circuit with an oxygen concentrator, the problem of argon accumulation would not occur if the circuit was opened periodically. In the semi-closed anesthesia circuit, argon would not accumulate if the fresh gas flows were at least twice the oxygen consumption. The Mercury[®] tube-valve-mask breathing circuit is a semi-open system; therefore the accumulation of argon will not occur unless the valve becomes incompetent.

Summary

The molecular sieve oxygen concentrator has demonstrated safe and reliable service (Friesen et al. 1999). Additionally, it has demonstrated the ability to remove many environmental pollutants as well as chemical warfare agents. This could be of

great utility in the mobile military arena. All oxygen concentrators produce argon enriched gas. Argon can accumulate in low flow closed systems and over time displace enough oxygen to cause patient distress. However, the Mercury[®] tube-valve-mask breathing circuit is a semi-open, non-rebreathing system preventing argon accumulation. Argon accumulation can occur only if the valve system fails.

The valve assembly used in the Mercury[®] tube-valve-mask breathing circuit is a reproduction of the Laerdal[®] Mark IV. Numerous studies have demonstrated this valve to be extremely reliable. The valve is inert to oxygen as well as the other gases used in anesthesia. Additionally, it is unaffected by accumulation of respiratory circuit moisture and is quite durable. The only reported failures of this valve are attributable to human error during reassembly. Reassembly error is eliminated in the current system because it is a single use circuit. One other major concern is resistance to flow and its effect on the work of breathing exerted by the patient. This valve has repeatedly demonstrated extremely low resistance to flow. The resistance is so low that infants can spontaneously ventilate through it for several hours without any clinical signs of tiring.

While the Mercury[®] tube-valve-mask breathing circuit performs differently than conventional high flow mask systems, the principles underlying its design are widely accepted. Oxygen delivery devices used today include facemasks, both rebreathing and non-rebreathing, venturi masks and resuscitation masks. All these masks provide reliable oxygen supplementation ranging from 40-90%. Unfortunately, all require high flow rates to provide concentrations of oxygen above 40% and to prevent rebreathing of expired alveolar gases. This high demand for oxygen is incompatible with today's highly mobile and rapidly moving military. In addition, current oxygen sources are extremely

expensive to procure and transport causing significant logistical problems. It is essential that an effective low flow oxygen delivery system replace currently used high flow systems. The current literature does not address the delivery of oxygen at low flow rates supplied from an oxygen concentrator through a tube-valve-mask breathing circuit. For this reason, we explored the performance of a low flow oxygen delivery system, the Mercury[®] tube-valve-mask breathing circuit, with oxygen supplied from an oxygen concentrator.

CHAPTER III

Methodology

The purpose of this study was to determine the efficacy of the Mercury[®] tube-valve-mask breathing circuit at two, three and four liter flow rates using an oxygen concentrator (Oxygen 93% USP) versus Oxygen 99% USP from standard hospital supply. The investigators used a double-blinded prospective, non-experimental, descriptive design. Determination of fraction of inspired oxygen was recorded for two different oxygen sources. Each subject participated in six trials. The trials consisted of two, three and four liter flow rates delivered via the Mercury[®] tube-valve-mask breathing circuit from both Oxygen 99% USP and Oxygen 93% USP sources in random order. This chapter details the population, sample and setting; instrumentation and procedure for data collection; protection of human subjects; the study design and the procedure for data analysis.

Study Design

This study was a prospective, non-experimental, descriptive design. A descriptive design is best used to observe, describe and document the fraction of inspired oxygen that is delivered to the patient through the Mercury[®] tube-valve-mask assembly using an oxygen concentrator or standard hospital oxygen. Based on our hypotheses, there were two groups with a total of six trials (three trials per group). A power analysis determined the sample size to be 18 subjects. The total sample size was 108 trials. Subjects were obtained from a convenience sample from the faculty and students of the US Army Graduate Program in Anesthesia Nursing at the Army Medical Department Center and School (AMEDDC&S) in San Antonio, Texas. A repeated measures technique was used

to aid in controlling the physiological variables that can occur between different subjects. Although the oxygen flow rate and the oxygen source were varied, the values were not being compared, so this was not an experimental design.

Population, Sample, and Setting

This study was conducted with a convenience sample of 18 healthy volunteers to include current students and faculty in United States Army Graduate Program in Anesthesia Nursing. The anesthesia nursing program is located at Fort Sam Houston, Texas. The study was conducted at the AMEDDC&S in the graduate nurse anesthesia laboratory, Willis Hall Room 2303.

The target population was active duty commissioned officers, both male and female, at least eighteen years of age with competence in the English language and in good general health. Good general health was defined as being free of symptoms from any diagnosed chronic or acute illness/disease. Exclusion criteria included: acute or chronic disease/illness excluding upper respiratory infections in the prior six months, pregnancy, or upper respiratory infections to include the common cold or flu within the prior two weeks. In addition, subjects were excluded from the study if systolic blood pressure was greater than 140 mmHg or less than 90 mmHg, diastolic blood pressure was greater than 90 mmHg or less than 50 mmHg, heart rate was greater than 100 beats/min or less than 50 beats/min, respiratory rate was greater than 30 breaths/min or less than 8 breaths/min and if temperature was greater than 99.6 degrees Fahrenheit. Any subject excluded for a health related concern was given the opportunity for referral to health care.

This study was performed using volunteers from a convenience sample. The faculty and students received information about the research design, procedures and the

criteria for inclusion in the study from an appointed ombudsman. After the instructional period, sign-up sheets were disseminated to identify interested parties. Interested parties were contacted and scheduled for an appointment to assess qualification for participation.

There were two groups with three trials each. The subjects served as their own control. The subjects were randomly assigned to which oxygen source they received first. The flow rates were randomly selected between 2 L/min, 3 L/min and 4 L/min. The design was double blinded so that neither the investigator collecting the data nor subject knew what oxygen source and flow rate were delivered. Each trial consisted of the subject breathing through the Mercury[®] tube-valve-mask breathing circuit.

Instrumentation

The equipment in this study included the Litton[®] Life Support flowmeter to accurately measure gas flow. The Ohmeda[®] 5250 RGM was used to measure inspiratory and expiratory oxygen and carbon dioxide, pulse oximetry, tidal volume and minute ventilation at the mask. The Ohmeda[®] 5120 oxygen analyzer was used to measure the fraction of oxygen in delivered gases at the source. The AirSep[®] New Life oxygen concentrator was used to deliver concentrated oxygen. An oxygen tank flowmeter measured the flow of oxygen from the tank source. A demographic questionnaire was used to document pertinent subject attributes. A data collection instrument was used to tabulate and record all results. The anesthesia department at Brooke Army Medical Center and the AMEDDC&S provided all equipment. All equipment was calibrated for accuracy and precision based on manufacturer's specifications. Routine maintenance and cleaning was conducted according to manufacturer's guidelines. If any equipment had

malfunctioned, it would have been turned in to the biomedical department at Brooke Army Medical Center for exchange or repair.

The Litton® Life Support flowmeter, distributed by Cole-Parmer Instrument Company, was used to accurately measure precise flows of oxygen. This flowmeter is designed to deliver precise and accurate gas flows up to 4.652 L/min with an error rate of +/- .05 L/min (e.g. D. Mulley, personal communication, March 22, 2001). The flowmeter uses a numeric scale ranging incrementally from 0-150 to determine flow rates. For example, when the flowmeter reads 150, the exact amount of oxygen delivered is 4.652 L/min as referenced by the correlation flow sheet distributed by Cole-Parmer Instrument Company (March 22, 2001). The correlation flow sheet is included in Appendix A. The flowmeter was calibrated before the first trial per manufacturer's recommendations. The flowmeter on the oxygen concentrator was used to adjust the rate of flow delivered to the Litton® Life Support flowmeter. The actual gas flow delivered to the subject was based on the 0-150 numeric reading on the Litton® Life Support flowmeter. The exact amount of oxygen in L/min was calculated using the correlation flow sheet.

The Ohmeda® 5250 RGM measures CO₂, N₂O and O₂ concentrations. The Ohmeda® 5250 RGM uses infrared spectrometry to measure the amount of CO₂, N₂O and anesthetic agents present in a gas sample (Ohmeda® 5250 Respiratory Gas Monitor Service Manual, 1990). A gas sample is drawn into the pneumatic system through the sample inlet and routed through conditioning components. The sample is then sent through a photometer for infrared analysis of the concentrations of CO₂ and N₂O. A signal processor board digitizes the information from the photometer and stores them for display. The measurement board sends waveform information and processes the signal

as a digital serial stream. An internal oxygen sensor measures oxygen concentrations. The solenoid sample valve actively samples gases from the circuit and based on the presence or absence of CO_2 in the sample, determines inspiratory and expiratory flow and oxygen concentration. The accuracy of gas analysis for the Ohmeda® 5250 RGM was reported as follows: end tidal $\text{CO}_2 \pm 0.3\%$, $\text{O}_2 \pm 2.0\%$ (0-60%) and $\text{O}_2 \pm 5.0\%$ (>60%) (Ohmeda® 5250 Respiratory Gas Monitor Service Manual, 1990). The day prior to data collection the Ohmeda® 5250 RGM was span calibrated with specific calibration gases provided by the manufacturer.

The Ohmeda® 5120 Oxygen Monitor User Manual states that this monitor uses a galvanic fuel cell to analyze oxygen concentration (Ohmeda® 5120 Oxygen Monitor Operation and Maintenance Manual, 1989). The galvanic cell is exposed to the fresh gas flow and oxygen diffuses through a membrane, enters the cell and oxidizes an electrode of base metal. This oxidation liberates hydroxide ions in concentrations proportional to the partial pressure of oxygen present in the gas mixture. The rate of this oxidation-reduction reaction is directly proportional to the ambient temperature. The sensor has an integral thermister in order to maintain constant temperature and reaction rate. As this process continues, the galvanic cell electrode is gradually consumed necessitating periodic replacement approximately every 12 months assuming exposure to 50% oxygen concentrations. The instrument can analyze oxygen concentrations from 0-100% and updates the measurement three times each second. The Ohmeda® 5120 reports 90% of the total change in oxygen concentration within 15 sec at 25 degrees Celsius. The drift is limited to $\pm 1\%$ over eight hours and displays linear function to within $\pm 1\%$ throughout its full scale. The monitor is temperature compensated between 15 and 40 degrees

Celsius but is operational at temperatures as low as 5 degrees Celsius (Ohmeda® 5120 Oxygen Monitor Operation and Maintenance Manual, 1989). The Ohmeda® 5120 was calibrated daily prior to data collection and at the conclusion of data collection.

According to the AirSep® product brochure (2001), the portable AirSep® oxygen concentrator used in this study concentrates oxygen by drawing room air into a compressor and forcing it through a molecular sieve canister where oxygen and nitrogen are separated. The oxygen (up to 95.5 %) is then delivered to an internal mixing tank for storage. The separated nitrogen is released back into the atmosphere. The quality of the concentrated oxygen is therapeutically equivalent to liquid oxygen or high pressure cylinder oxygen systems (Petty et al., 1979).

The AirSep® unit weighs 54 pounds and is powered electrically (120 VAC, 60Hz, 4.0 amps). Based on an atmospheric pressure of 14.7 psia at 21 degrees Celsius, the AirSep® concentrator can deliver 95% oxygen \pm 3% at 1–3 L/min and 90% oxygen \pm 3% at a maximum of 6 L/min. To ensure oxygen quality, the concentrator is equipped with the EcoCheck® oxygen monitor that responds immediately to changes in oxygen purity. An amber light illuminates if the oxygen purity falls below 85%. If this condition lasts longer than 15 minutes, an audible alarm sounds (AirSep® product brochure, 2001).

A demographic questionnaire (Appendix B) and a data collection tool (Appendix C) were developed to allow the investigators to record demographic data, screen subjects for pertinent health history and to record data generated by the study.

Procedure for Data Collection

This study uses two sources of oxygen. The sources of oxygen were oxygen supplied from a medical gas supply company and oxygen supplied from the AirSep[®] oxygen concentrator. Subjects served as their own control. The subjects were randomly assigned to which oxygen source they received first. The flow rates were randomly selected between 2 L/min, 3 L/min and 4 L/min. The design was double blinded so that neither investigator nor subject knew what oxygen source was delivered. Two investigators were in the room with each subject. One investigator was responsible for recording the FiO_2 delivered and the other investigator adjusted the flow rates and the sources of oxygen. The adjusting investigator was located behind a partition so the recording investigator did not have knowledge of which source was being utilized. Each trial consisted of the subject breathing the selected source and flow rate through the Mercury[®] tube-valve-mask breathing circuit until a sustained FiO_2 was obtained. A sustained FiO_2 was defined as no greater than a 10% change in FiO_2 over a three-minute period. Data collection began when the oxygen was turned on. Once the sustained FiO_2 was determined a three-minute trial began. The trial ended in 30 minutes if a $\text{FiO}_2 \pm 10\%$ was not sustained.

The Ohmeda[®] 5250 RGM gas analyzer provided constant readings of the oxygen and carbon dioxide content of the inspiratory and expiratory gases in the Mercury[®] tube-valve-mask breathing circuit. The analyzer was calibrated to room air and to 100% oxygen prior to trials. For calibration purposes, a separate cylinder containing 100% oxygen was used.

A baseline oxygen concentration level was obtained from the oxygen tank and/or oxygen concentrator. The Ohmeda® 5120 Oxygen Analyzer measured baseline oxygen content from the oxygen concentrator. By convention, it is understood that the remaining gases were nitrogen, argon and some trace gases. If the baseline values were not obtained, the trial would not begin. The same oxygen concentrator was used for all trials. If the oxygen concentrator detected an 85% oxygen concentration the trial would have been stopped. For each trial, single use circuits were used. A minimum of 21% oxygen was delivered to the subject at all times. The FiO_2 delivered to the subject was recorded every 30 seconds.

Each subject had continuous monitoring of electrocardiogram (EKG), pulse oximetry, FiO_2 , tidal volume and end tidal carbon dioxide. Heart rate, respiratory rate, temperature and non-invasive blood pressure were recorded at the beginning and conclusion of the trial. Termination criteria: the subject deviated from their baseline heart rate by 20%, any abnormalities were observed or recorded from the EKG, pulse oximeter or end tidal carbon dioxide analysis; complaints of any untoward symptoms; or subject requested to stop. The investigators collected all data and monitored the subjects throughout the trial. If the subject had required immediate medical care beyond the capabilities of the researchers, emergency medical services would have been called. No health related concerns were noted.

Internal and External Validity

Regardless of the design, there are threats inherent to the internal and external validity of all studies. According to Polit and Hungler, (1999) internal validity can be jeopardized by several factors including: history, selection, maturation, testing,

instrumentation and mortality. History refers to outside events that affect the dependent variable at the same time the independent variable is being changed and evaluated. Maturation refers to the changes in the dependent variable, which occur naturally as a result of the passage of time. Normal wound healing is an excellent example of this effect. Mortality is the loss of subjects after they have been entered in the study for whatever reason. Mortality tends to increase as the length of time the subjects are required to be in the study increases. This study limited the influence of history, maturation and mortality by completing the data collection for each subject in a maximum of three hours. Because this study was done with a convenience sample, a selection bias may have been introduced. A selection bias is the assumption that the sample was not representative of the population.

Instrumentation threats are sources of error resulting directly from the precision and accuracy of the instrument, or from error in reading output from the instrument. All instruments used in this study met current standards for accuracy and precision at the time of the study. All instruments with the exception of the Litton® Life Medical Flowmeter provided digital output limiting investigator error to transcription errors. The investigators were tested on their ability to consistently measure flow rate values from the Litton® Life Medical Flowmeter until inter-rater reliability was obtained. Inter-rater reliability was measured as a function of percent agreement among the investigators. The minimal acceptable level of inter-rater reliability was preset at 90%. All investigators were instructed to measure the flow rate at the midpoint of the ball float. One investigator was responsible for ensuring that all investigators were reading the

flowmeter accurately. After a series of measurement trials, 100% inter-rater reliability was obtained among all investigators.

The final threat to internal validity is testing effects. These are the changes the subject makes simply because they have been exposed to multiple tests over time. In this study the subjects were exposed to multiple tests at different flow rates, which may have affected the results over time. Each subject was counseled to breathe normally and the test environment was manipulated to promote subject comfort in an effort to control this threat. The treatment order was randomized to minimize the testing effect from consistently affecting the results of a particular flow rate over time.

External validity describes the degree to which the study results can be generalized to the target population. Five threats to external validity exist and must be controlled in order for the study results to be generalizable to a larger population (Polit & Hungler, 1999). These threats are: the Hawthorne effect, novelty effects, the variance caused by the combined action of history and the independent variable, investigator effects and measurement effects. The Hawthorne effect describes the changes subjects make when they are aware they are being observed. Novelty effects describe the changes subjects may create simply by virtue of the fact that the treatment is new. Their response would be expected to change as the novelty of the new approach fades. To control these effects, the subjects were instructed to breathe normally and the environment was controlled to promote subject comfort and distraction. The interaction of the independent variable and outside events, or history, can play an important role in a prolonged study. We sought to limit this variance by performing all six trials successively in one appointment, which limited the data collection time to no more than three hours per

subject. Investigator effects are those variances caused by the investigator's verbal and non-verbal actions. In order to limit this effect, the study was double blinded and a second investigator, not involved with the data collection, effected all manipulations of the independent variable. Measurement effects describe the change in the dependent variable caused by the design and methods of the study. People not subjected to the same pre-test and post-test environment could be expected to react differently from the subjects in the study. This effect is particularly problematic if the study subjects require significant teaching/coaching or if they are retested on the same material after the treatment is received. Variance due to measurement was limited in this study because the subject teaching was limited to reminders to breathe normally and the results of the treatment were objective measurements of physiologic functions.

Protection of Human Subjects

After receiving approval from the Brooke Army Medical Center and UTHSC-H Institutional Review Boards (IRB), informed consent was obtained from each subject after a thorough briefing describing the study. The risks and benefits were described to the subjects as outlined in the informed consent (Appendix D). Each subject was offered a copy of the informed consent form. Careful screening and monitoring of the subjects minimized potential risks. Comfort of the subject during each trial was maintained with environmental adjustments (positioning, room temperature, music and lighting) as needed. The subjects were notified of any changes in their condition throughout the trials. Results of the study were disseminated in accordance with the policies of the University of Texas Health Science Center at Houston and the United States Army. Confidentiality was maintained at all times. Subjects were assigned numbers and

identified by that number on all records and documents. Only the principal investigator had the original name list and assigned numbers. This information was secured in a locked cabinet in the Department of Nursing at the AMEDDC&S. The data was stored in a locked box in the anesthesia classroom. Data was released as statistical data. Confidentiality of subjects in this study will be preserved in any future publications. All records will be kept in a secure location by the principal investigator for five years after the completion of the study.

There was little risk to the subject. Some subjects experienced minor discomfort from wearing a facemask. The risk of delivering a hypoxic gas mixture to the subject was minimal. Safeguards were maintained throughout the study to assure that the subject did not receive a hypoxic mixture. The investigators continuously observed the subjects' response to the mask. Termination of the trial would have occurred if any deviation from normal parameters in the measurement of vital signs, EKG and pulse oximetry were noted. A senior faculty member was available during the trials. Emergency medical services would have been activated if needed.

Procedure for Data Analysis

The question we wished to address is nominal level data: did the FiO_2 meet or exceed the predicted FiO_2 ? For each hypothesis stated, a goodness-of-fit statistical analysis was performed to determine if a set of observed data corresponded to a theoretical distribution of the data. A power analysis was done to determine the appropriate sample size for the study. A sample size of 18 subjects was calculated using the statistical program G Power based on an effect size of 0.7, an alpha of 0.05, a power of 0.83 and one degree of freedom. The data was analyzed using descriptive statistics

and a goodness-of-fit test. The goodness-of-fit test was used to determine if the collected data met the predetermined values for expected FiO_2 at each flow rate. A comparison of the flow rates with the minute volume, tidal volume, respiratory rate and BMI was calculated and graphed. The expected FiO_2 at different flow rates were based on clinical experience in the field of anesthesia provided by Colonel Steven Janny, Chief Nurse Anesthetist at Brooke Army Medical Center. COL Janny predicted that 85% of all tested subjects would have an FiO_2 of 0.40 at 2 L/min, 0.50 at 3 L/min, and 0.60 at 4 L/min using Oxygen 93% USP from an oxygen concentrator. A large effect size was chosen because we expected that most of the subjects would achieve these criteria. The demographic data collected included age, height, weight and gender which were used to calculate BMI, ideal body weight and expected tidal volumes. The data collected was used to determine the efficacy of the Mercury® tube-valve-mask breathing circuit at two, three and four liter flow rates.

CHAPTER IV

Analysis of Data

This chapter discusses the data collected by the investigators in this study. Sample characteristics, findings and secondary analyses will be addressed in detail. SPSS[®] version 10.13 for Windows[®] was used for all statistical analysis.

Description of Sample

This study was conducted using a convenience sample of 18 healthy volunteers consisting of students and faculty at the United States Army Graduate Program in Anesthesia Nursing. All subjects were active duty commissioned officers, both male and female, at least 18 years of age with competence in the English language and in good general health. During the health history interview, the following demographic data were collected: age, gender, height and weight. The demographic data were used to calculate the following physiologic parameters: Body Mass Index (BMI), Ideal Body Weight (IBW) and Expected Tidal Volume (EV_t). In addition, the RGM was used to collect the actual values for Respiratory Rate (RR), Tidal Volume (V_t), Minute Volume (V_e) and FiO_2 . Table 1 illustrates the characteristics of the 18 subjects (14 males, 4 females).

Each subject participated in six trials during which data was collected at 30-second intervals. The trials consisted of two, three and four liter flow rates delivered in random order via the Mercury[®] tube-valve-mask breathing circuit from both Oxygen 99% USP and Oxygen 93% USP (see Table 2). Data collection continued at each flow rate and source combination until a three-minute period of sustained FiO_2 was reached. All subjects were able to attain a sustained FiO_2 within the allotted 30 minute period. However, the results of this study indicate that 85% of subjects did not reach the

predicted FiO_2 of 0.4 at 2L, 0.5 at 3L and 0.6 at 4L. Only one subject was able to attain the predicted FiO_2 at each of the flow rates and oxygen source combinations

Table 1

Descriptive Statistics of Demographic Data

Demographic measurements	Range	<u>M</u>	<u>SD</u>
Age (yr)	28-43	34	5
Height (in)	64-77	69	3
Weight (kg)	56-108	83	14
Ideal Body Weight (kg)	57-94	74	10
Body Mass Index (kg/cm^2)	19-32	261	3
Tidal Volume (ml)	437-1317	796	239
Expected Tidal Volume (ml)	375-624	493	66
Respiratory Rate (bpm)	5-20	11	3
Minute Ventilation (L)	4-11	8.2	1.3

Note. BMI = kg/cm^2 , IBW (male) = $6 (\text{height}_{(\text{in})} - 60) + 106$,
 IBW (female) = $5 (\text{height}_{(\text{in})} - 60) + 105$, $\text{EV}_t = 3 (\text{IBW}_{(\text{lbs})})$

Table 2

Subjects Treatment Order of Flow Rate and Source

Subject	2L/min O ₂ 93%	3L/min O ₂ 93%	4L/min O ₂ 93%	2L/min O ₂ 99%	3L/min O ₂ 99%	4L/min O ₂ 99%
1	6	5	2	1	3	4
2	1	4	3	6	5	2
3	1	3	5	2	6	4
4	2	5	6	4	1	3
5	3	5	1	6	4	2
6	4	6	1	5	3	2
7	1	3	4	2	5	6
8	5	6	2	1	4	3
9	2	5	4	6	3	1
10	1	4	3	6	5	2
11	3	4	2	5	6	1
12	5	3	2	4	1	6
13	4	2	1	3	5	6
14	3	2	1	4	6	5
15	2	3	6	1	4	5
16	4	6	1	5	3	2
17	1	5	3	6	4	2
18	4	2	6	5	3	1

Overall, the subjects required an average of 106 seconds to reach a sustained FiO_2 . The time required to reach a sustained FiO_2 ranged from zero to 1050 seconds. A value of zero seconds indicates that it took less than 30-seconds for a subject to reach a sustained FiO_2 during exposure to a particular flow rate and source since data were

collected at 30-second intervals. Table 3 summarizes the average time that it took each subject to reach a sustained FiO_2 at each flow rate and source.

Table 3

Time (sec.) to Reach a Sustained FiO_2

Subject	2L/min O ₂ 93%	3L/min O ₂ 93%	4L/min O ₂ 93%	2L/min O ₂ 99%	3L/min O ₂ 99%	4L/min O ₂ 99%	<u>M</u> sec.
1	30	60	60	90	30	0	45
2	60	30	0	60	0	0	25
3	30	30	60	0	30	60	35
4	30	90	30	30	30	0	35
5	60	1050	90	90	390	30	285
6	90	210	210	60	0	270	140
7	210	330	0	150	120	480	215
8	120	90	60	90	0	60	70
9	150	60	120	0	60	60	75
10	30	60	0	30	0	90	35
11	0	90	60	30	150	90	70
12	0	390	720	150	480	150	315
13	0	30	120	60	60	30	50
14	30	30	30	0	30	30	25
15	0	0	0	30	0	0	5
16	30	30	570	90	120	480	220
17	90	180	540	30	30	30	150
18	60	60	120	300	90	60	115
<u>M (sec.)</u>	57	157	155	72	90	107	106

The average time of exposure to experimental conditions was 1,717 seconds (28.6 min), while the minimum time was 1,110 seconds (18.5 min) and the maximum time was 2,970 seconds (49.5 min). The length of time that each subject was exposed to the treatment conditions at each flow rate and source is summarized in Table 4.

Table 4

Time (sec.) Exposed to Experimental Conditions

Subject	2L/min O ₂ 93%	3L/min O ₂ 93%	4L/min O ₂ 93%	2L/min O ₂ 99%	3L/min O ₂ 99%	4L/min O ₂ 99%	<u>M</u> sec.
1	210	240	240	270	210	180	1350
2	240	210	180	240	180	180	1230
3	210	210	240	180	210	240	1290
4	210	270	210	210	210	180	1290
5	240	1230	270	270	570	210	2790
6	270	390	390	240	180	450	1920
7	390	510	180	330	300	660	2370
8	300	270	240	270	180	240	1500
9	330	240	300	180	240	240	1530
10	210	240	180	210	180	270	1290
11	180	270	240	210	330	270	1500
12	180	570	900	330	660	330	2970
13	180	210	300	240	240	210	1380
14	210	210	210	180	210	210	1230
15	180	180	180	210	180	180	1110
16	210	210	750	270	300	660	2400
17	270	360	720	210	210	210	1980
18	240	240	300	480	270	240	1770

Findings

A goodness-of-fit test was used to determine if 85% of the subjects tested reached the expected FiO_2 for each stated hypothesis. Less than 85% of the subjects tested reached the FiO_2 criterion at 2 L/min, 3 L/min and 4 L/min.

Our first hypothesis stated that the Mercury[®] tube-valve-mask breathing circuit would deliver a FiO_2 of 0.40 when supplied with Oxygen 93% USP or Oxygen 99% USP at 2 L/min. We rejected this hypothesis because the prediction that 85% of our subjects would achieve a FiO_2 of 0.40 was not supported. Only two subjects (11%) receiving Oxygen 93% USP (see Table 5) and four subjects (22%) receiving Oxygen 99% USP (see Table 6) achieved a FiO_2 of 0.40. The mean FiO_2 at 2L/min was 0.35 (SD =0.04, range 0.29-0.45) with Oxygen 93% USP and 0.36 (SD =0.03, range 0.31-0.42) with Oxygen 99% USP.

Table 5

Oxygen 93% USP at 2 L/min
(FiO_2 criterion =0.40)

	<u>Observed</u>		<u>Expected</u>	
	N	Proportion	N	Proportion
Reached expected FiO_2 ?				
Yes	2	.11	15.3	.85
No	16	.89	2.7	.15
Total	18	1.00	18	1.00

Table 6
Oxygen 99% USP at 2 L/min
(FiO₂ criterion =0.40)

	Observed		Expected	
	N	Proportion	N	Proportion
Reached expected FiO ₂ ?				
Yes	4	.22	15.3	.85
No	14	.78	2.7	.15
Total	18	1.00	18	1.00

Our second hypothesis stated that the Mercury[®] tube-valve-mask breathing circuit would deliver a FiO₂ of 0.50 when supplied with Oxygen 93% USP or Oxygen 99% USP at 3 L/min. We rejected this hypothesis because the prediction that 85% of our subjects would achieve a FiO₂ of 0.50 was not supported. Only three subjects (17%) receiving Oxygen 93% USP (see Table 7) and two subjects (11%) receiving Oxygen 99% USP (see Table 8) achieved a FiO₂ of 0.50. The mean FiO₂ at 3 L/min was 0.45 (SD=0.06, range 0.37-0.61) with Oxygen 93% USP and 0.45 (SD=0.04, range 0.38-0.53) with Oxygen 99% USP.

Table 7
Oxygen 93% USP at 3 L/min
(FiO₂ criterion =0.50)

	Observed		Expected	
	N	Proportion	N	Proportion
Reached expected FiO ₂ ?				
Yes	3	.17	15.3	.85
No	15	.83	2.7	.15
Total	18	1.00	18	1.00

Table 8

Oxygen 99% USP at 3 L/min
(FiO₂ criterion =0.50)

	Observed		Expected	
	N	Proportion	N	Proportion
Reached expected FiO ₂ ?				
Yes	2	.11	15.3	.85
No	16	.80	2.7	.15
Total	18	1.00	18	1.00

Our third hypothesis stated that the Mercury[®] tube-valve-mask breathing circuit would deliver a FiO₂ of 0.60 when supplied with Oxygen 93% USP or Oxygen 99% USP at 4 L/min. We rejected this hypothesis because the prediction that 85% of our subjects would achieve a FiO₂ of 0.60 was not supported. Only one subject (6%) receiving Oxygen 93% USP (see Table 9) and three subjects (17%) receiving Oxygen 99% USP (see Table 10) achieved a FiO₂ of 0.60. The mean FiO₂ at 4 L/min was 0.52 (SD=0.08, range 0.40-0.74) with Oxygen 93% USP and 0.53 (SD=0.08, range 0.42-0.77) with Oxygen 99% USP.

Table 9

Oxygen 93% USP at 4 L/min
(FiO₂ criterion =0.60)

	Observed		Expected	
	N	Proportion	N	Proportion
Reached expected FiO ₂ ?				
Yes	1	.06	15.3	.85
No	17	.94	2.7	.15
Total	18	1.00	18	1.00

Table 10

Oxygen 99% USP at 4 L/min
(FiO₂ criterion =0.60)

Reached expected FiO ₂ ?	Observed		Expected	
	N	Proportion	N	Proportion
Yes	3	.17	15.3	.85
No	15	.83	2.7	.15
Total	18	1.00	18	1.00

Secondary Analyses

We conducted secondary analysis comparing the FiO₂ with subjects receiving Oxygen 93% USP and Oxygen 99% USP. Our secondary analysis also included looking at correlations between FiO₂ and RR, V_t and V_e. The correlations between BMI, IBW and EV_t and FiO₂ were also calculated from our demographic data.

As shown in Figure 4, when oxygen is delivered using the Mercury[®] tube-valve-mask breathing circuit, the average FiO₂ was similar whether using Oxygen 93% USP or Oxygen 99% USP at 2 L/min, 3 L/min and 4 L/min flow rates.

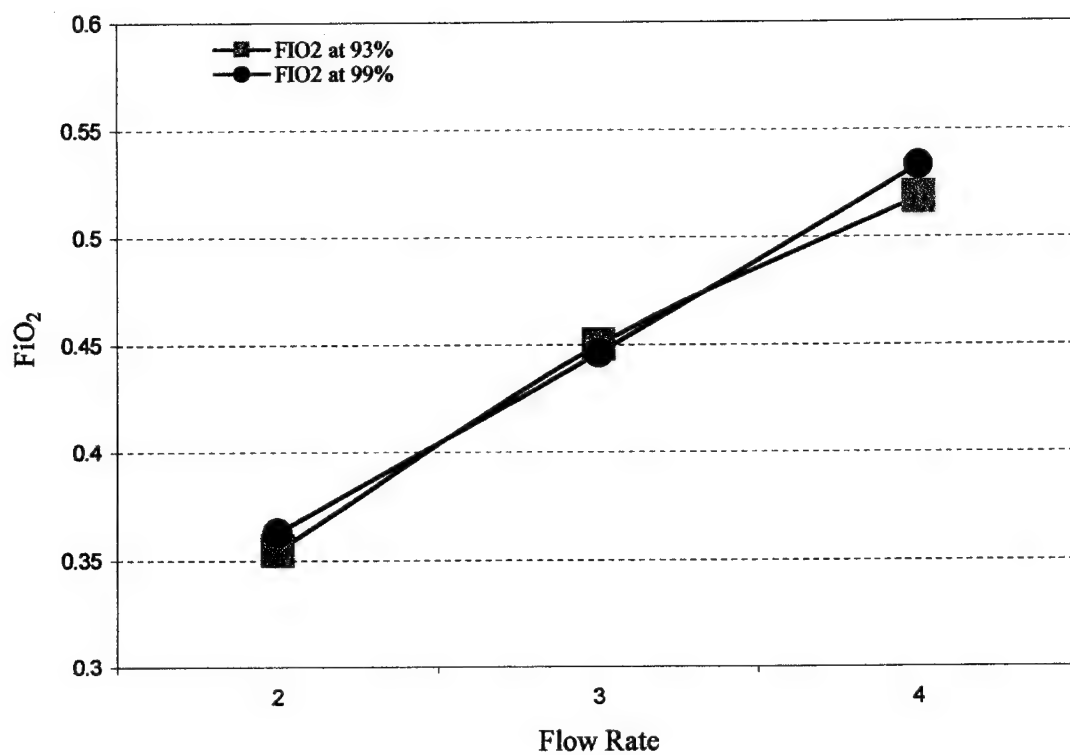


Figure 4. Comparison of Flow Rate and Oxygen Source

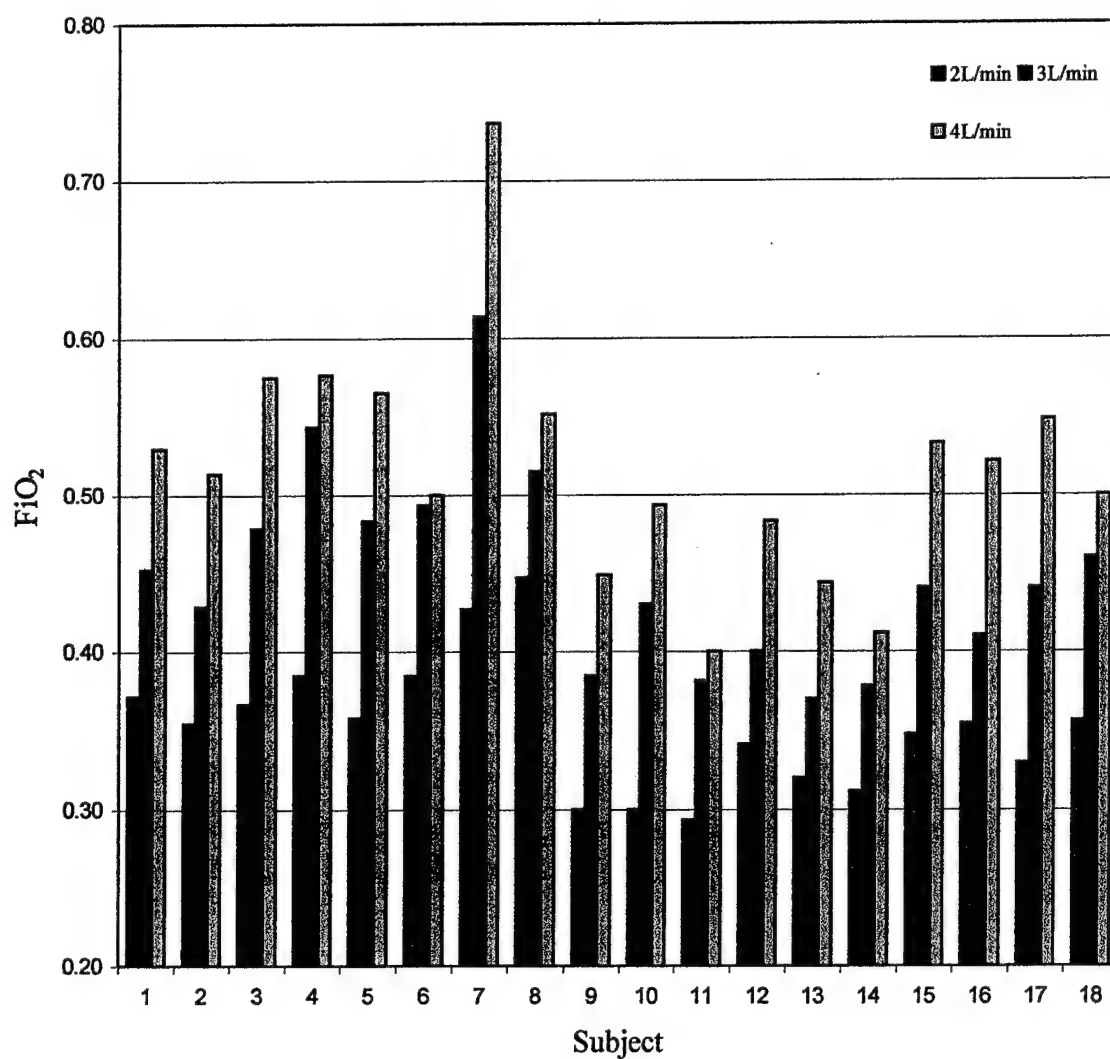


Figure 5. Comparison of FiO_2 and Flow Rate at Oxygen 93% USP

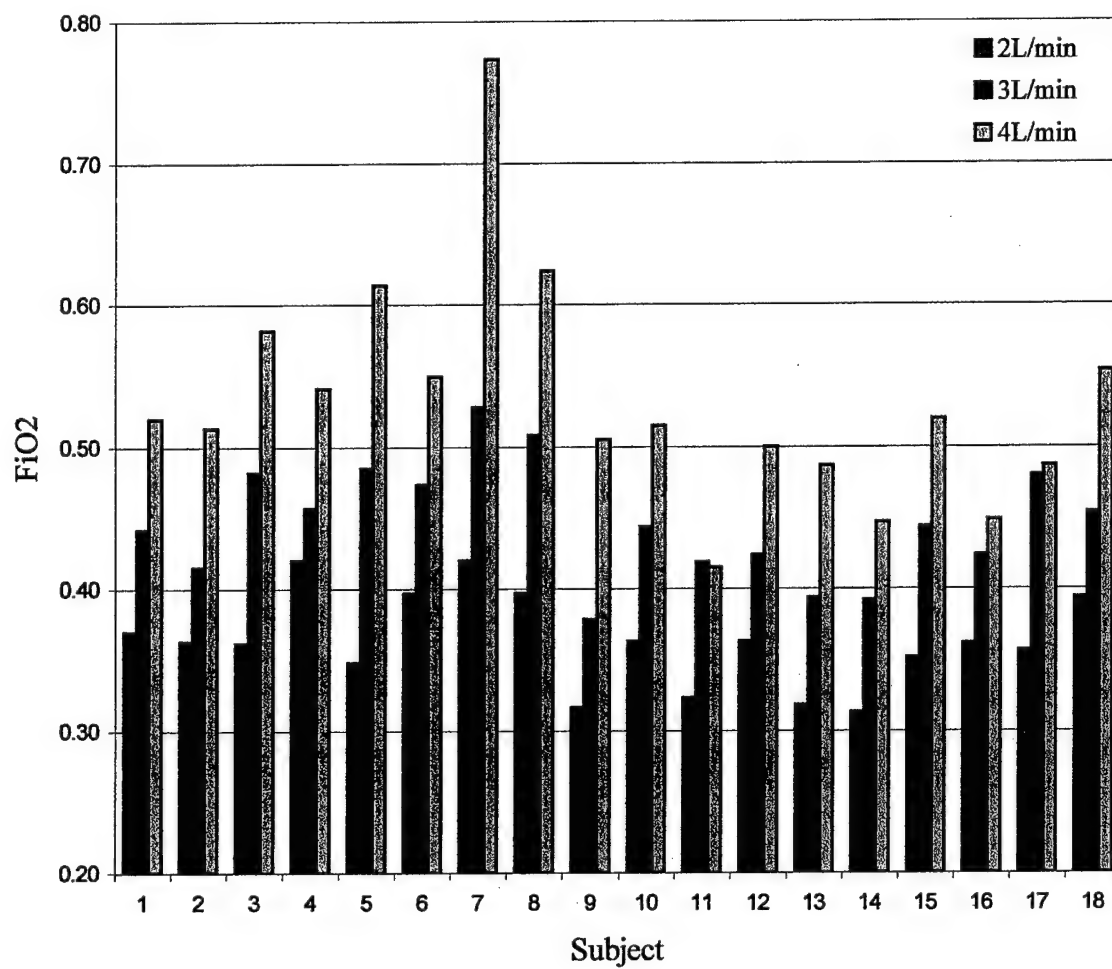


Figure 6. Comparison of FiO_2 and Flow Rate at Oxygen 99% USP

Pearson product moment correlation coefficients were calculated to examine the relationship between respiratory rate and FiO_2 (see Table 11). A significant negative correlation was found at 2 L/min flow rate using Oxygen 99% USP ($r = -0.54$, $p = 0.02$). At all other flow rates, respiratory rate did not have a significant correlation with FiO_2 using either oxygen source. No significant correlation was found between tidal volume and FiO_2 at any flow rate using either oxygen source. Although respiratory rate and tidal volume did not yield significant correlations individually, V_e and FiO_2 were significantly negatively correlated. The only combinations of flow rate and source that did not yield significant correlations were 2 L/min and 3 L/min with Oxygen 99% USP. Figures 5 and 6 illustrate the relationship between minute ventilation and FiO_2 .

Table 11

Correlations between Respiratory Rate (RR), Tidal Volume (V_t),
Minute Volume (V_e) and FiO_2

Parameter	2 L/min O ₂ 93% (r,p)	3 L/min O ₂ 93% (r,p)	4 L/min O ₂ 93% (r,p)	2 L/min O ₂ 99% (r,p)	3 L/min O ₂ 99% (r,p)	4 L/min O ₂ 99% (r,p)
RR	-0.38, 0.12	-0.30, 0.23	-0.33, 0.18	-0.54, 0.02*	-0.18, 0.49	-0.28, 0.26
V_t	-0.25, 0.32	-0.10, 0.69	-0.08, 0.74	-0.31, 0.22	-0.03, 0.90	-0.15, 0.56
V_e	-0.52, .03*	-0.55, 0.02*	-0.61, 0.01*	-0.41, 0.09	-0.23, 0.35	-0.58, 0.01*

Note. * = significant p-value

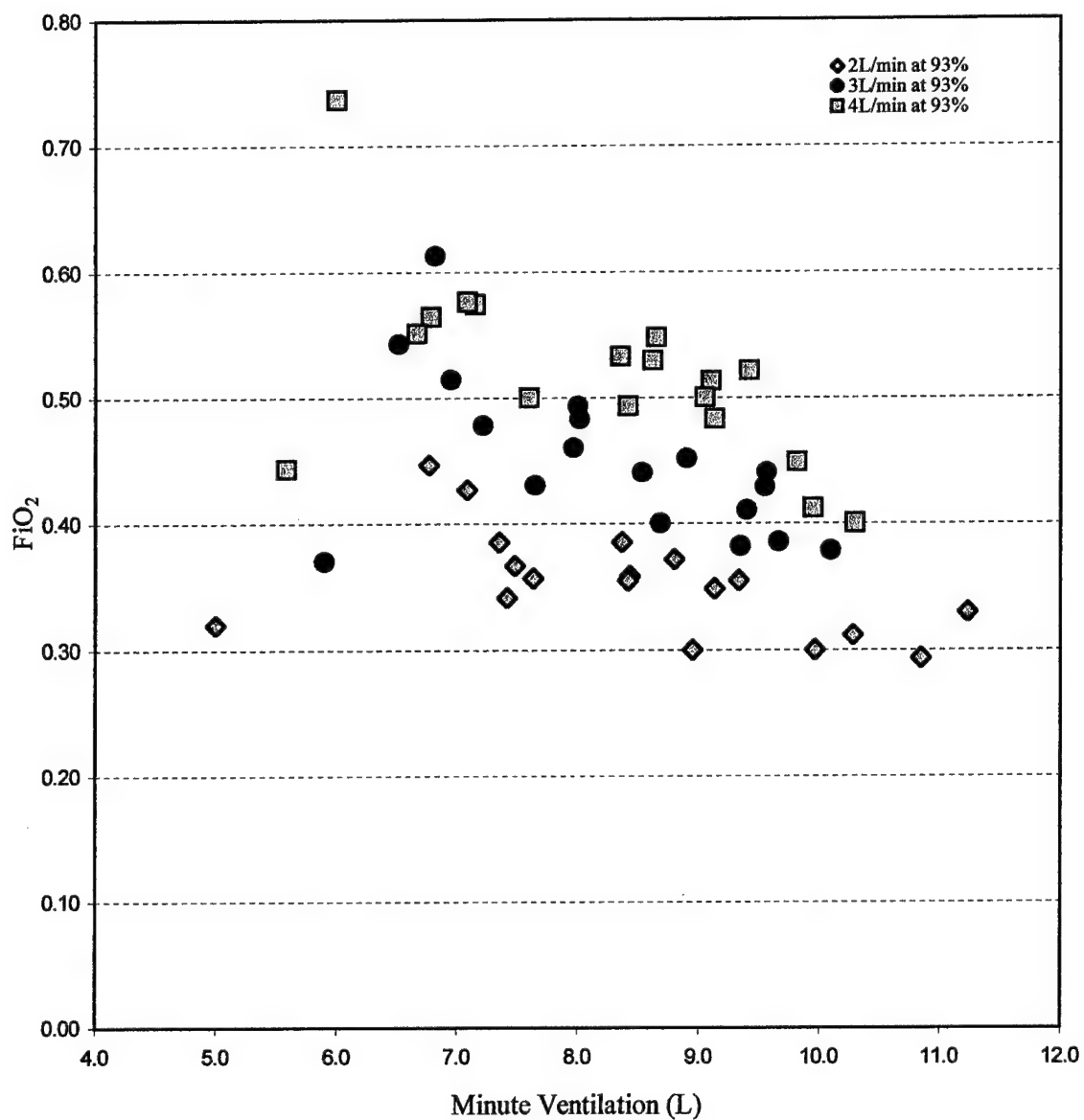


Figure 7. Correlation between FiO_2 and Minute Ventilation with Oxygen 93% USP

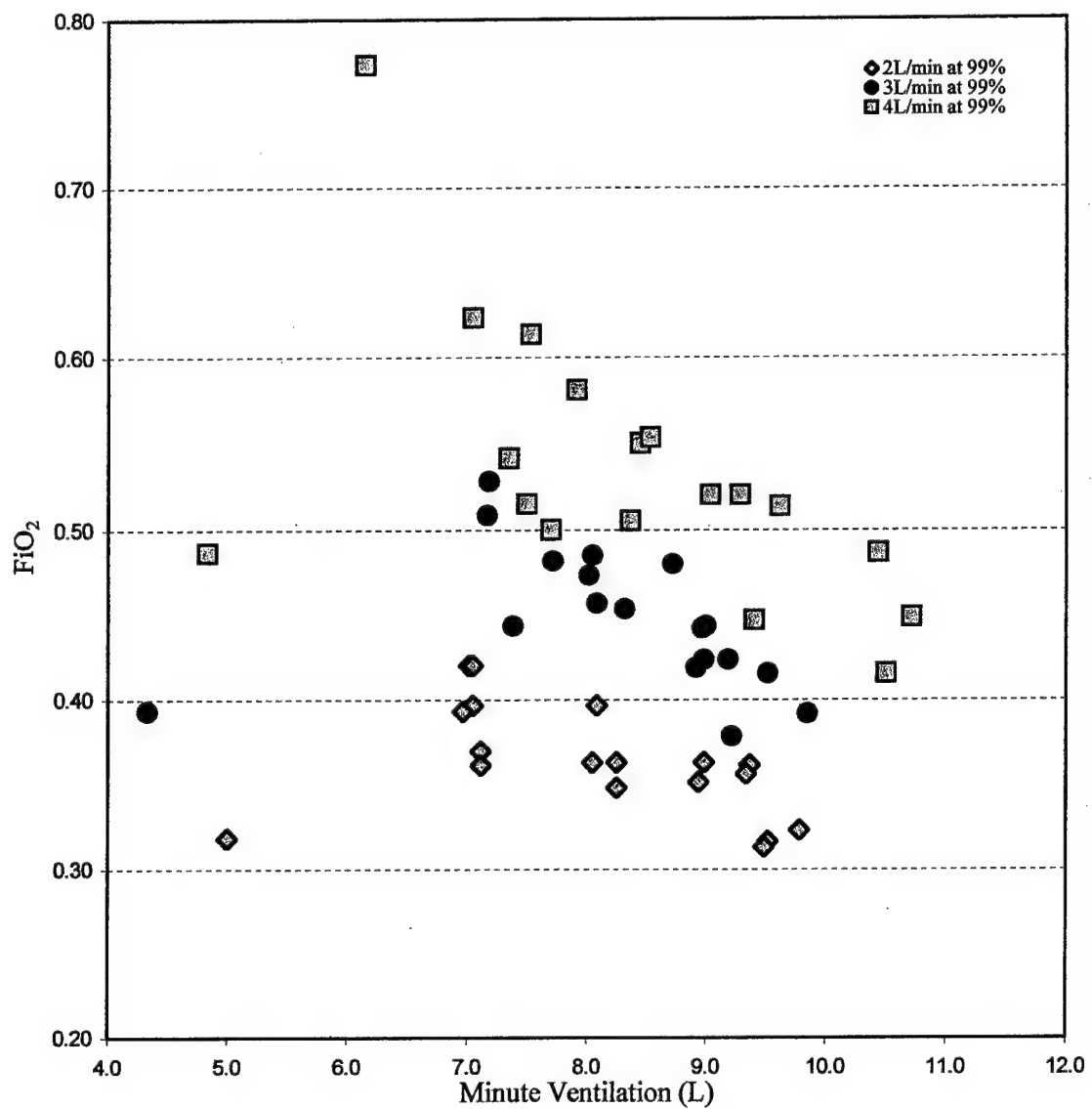


Figure 8. Correlation between FiO_2 and Minute Ventilation with Oxygen 99% USP

When the correlation between body mass index and FiO_2 was examined, we found that body mass index does not correlate with FiO_2 using either Oxygen 93% USP or Oxygen 99% USP. Ideal body weight and predicted tidal volume were both found to have significant negative correlations with FiO_2 at all combinations of flow rates and oxygen sources. Table 12 summarizes the relationships between FiO_2 and body mass index, ideal body weight and expected tidal volume. Expected tidal volume and ideal body weight were identically correlated with FiO_2 . This phenomenon can be explained by the fact that expected tidal volume is a function of ideal body weight. Figures 5 and 6 illustrate the relationships between FiO_2 and expected tidal volume. The relationship between FiO_2 and ideal body weight is illustrated in Figures 9 and 10.

Table 12

Correlations between Body Mass Index (BMI), Ideal Body Weight (IBW), Expected Tidal Volume (EV_t) and FiO_2

Parameter	2 L/min O_2 93% (r,p)	3 L/min O_2 93% (r,p)	4 L/min O_2 93% (r,p)	2 L/min O_2 99% (r,p)	3 L/min O_2 99% (r,p)	4 L/min O_2 99% (r,p)
BMI	-0.14, 0.58	-0.14, 0.57	-0.30, 0.22	-0.21, 0.40	-0.32, 0.20	-0.22, 0.38
IBW	-0.46, 0.05*	-0.58, 0.01*	-0.64, <0.01*	-0.49, 0.04*	-0.52, 0.03*	-0.48, 0.04*
EV_t	-0.46, 0.05*	-0.58, 0.01*	-0.64, <0.01*	-0.49, 0.04*	-0.52, 0.03*	-0.48, 0.04*

Note. * = significant p-value

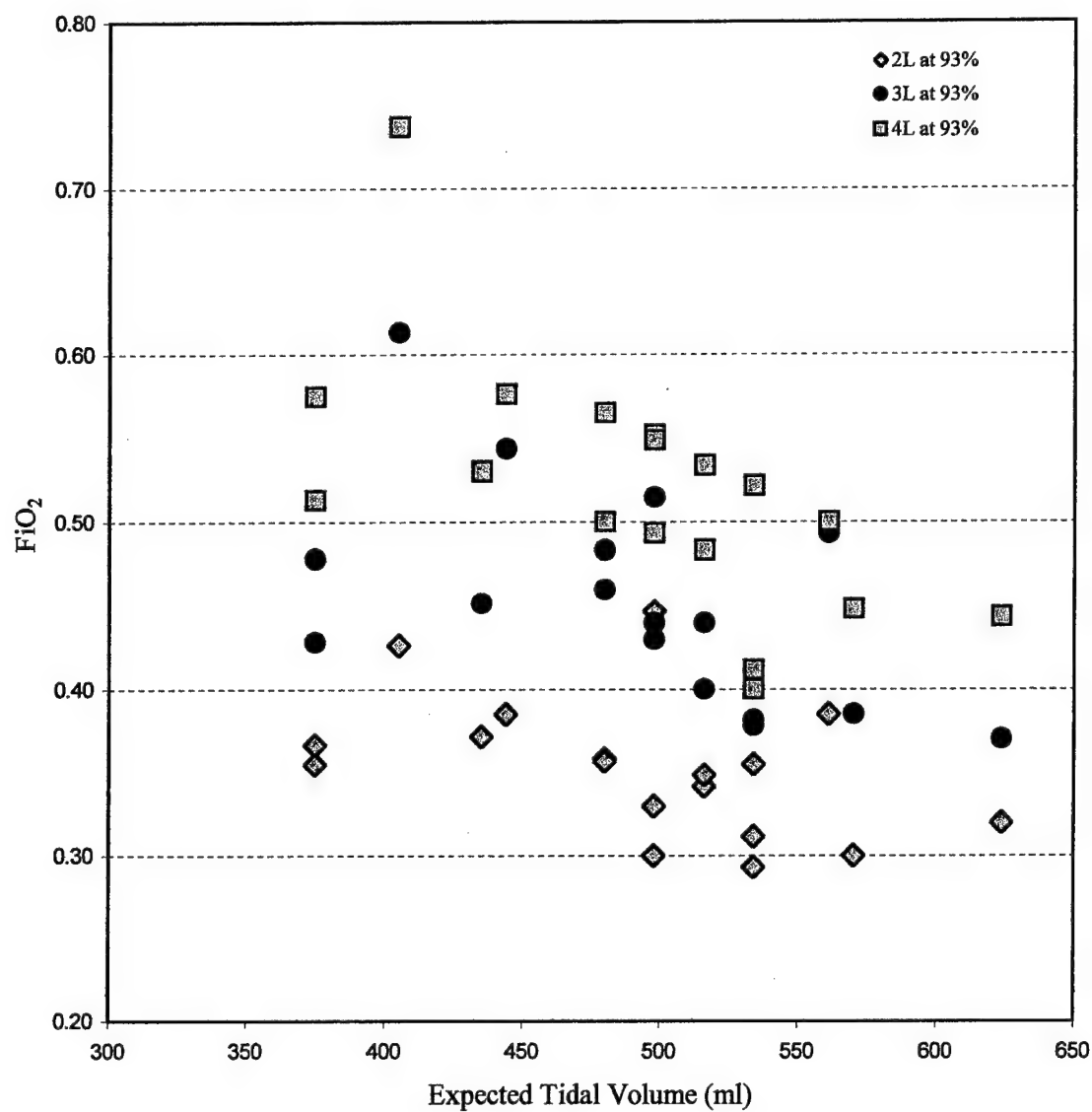


Figure 9. Correlation between FiO_2 and Expected Tidal Volume with Oxygen 93% USP

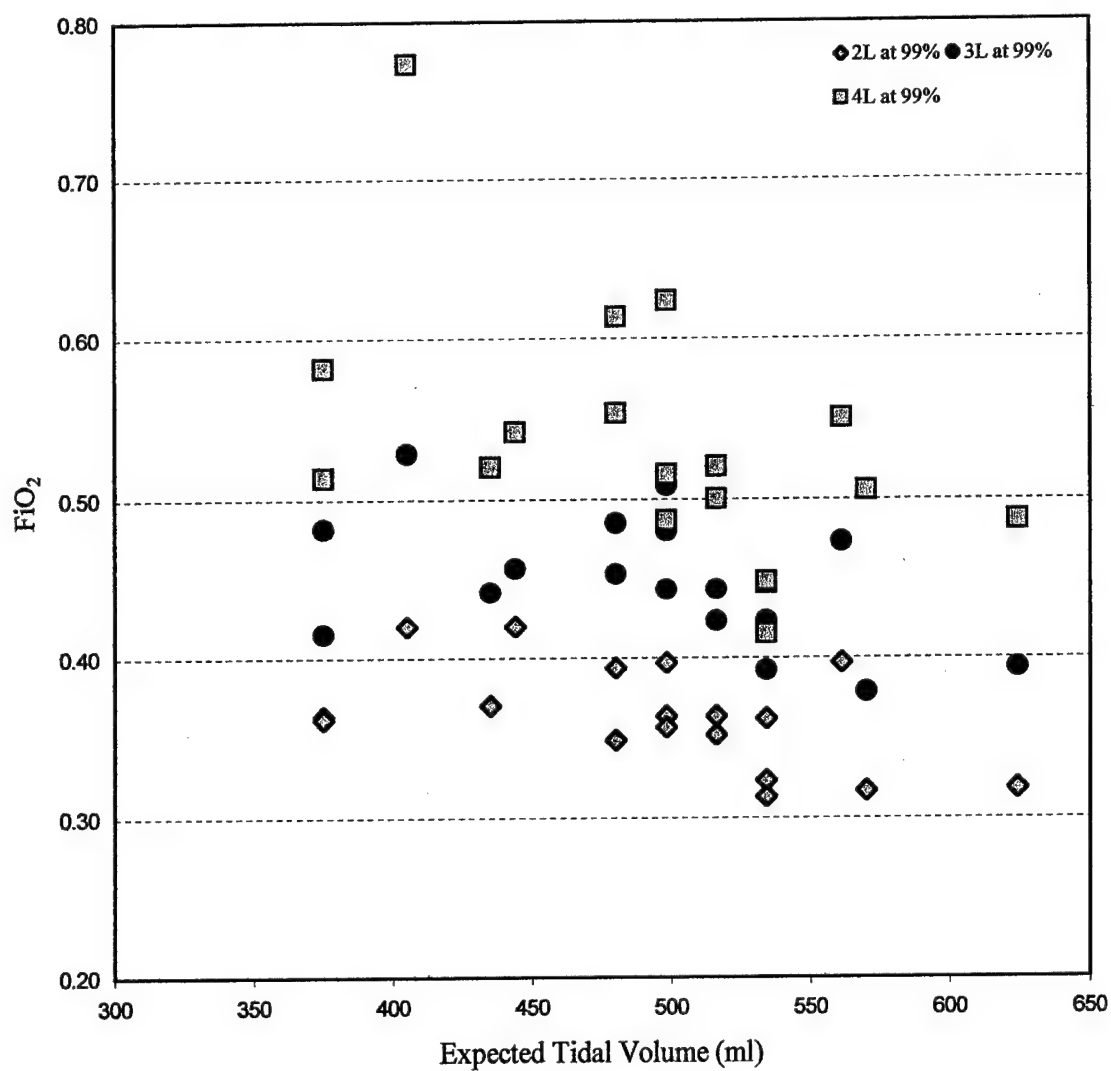


Figure 10. Correlation between FiO_2 and Expected Tidal Volume with Oxygen 99% USP

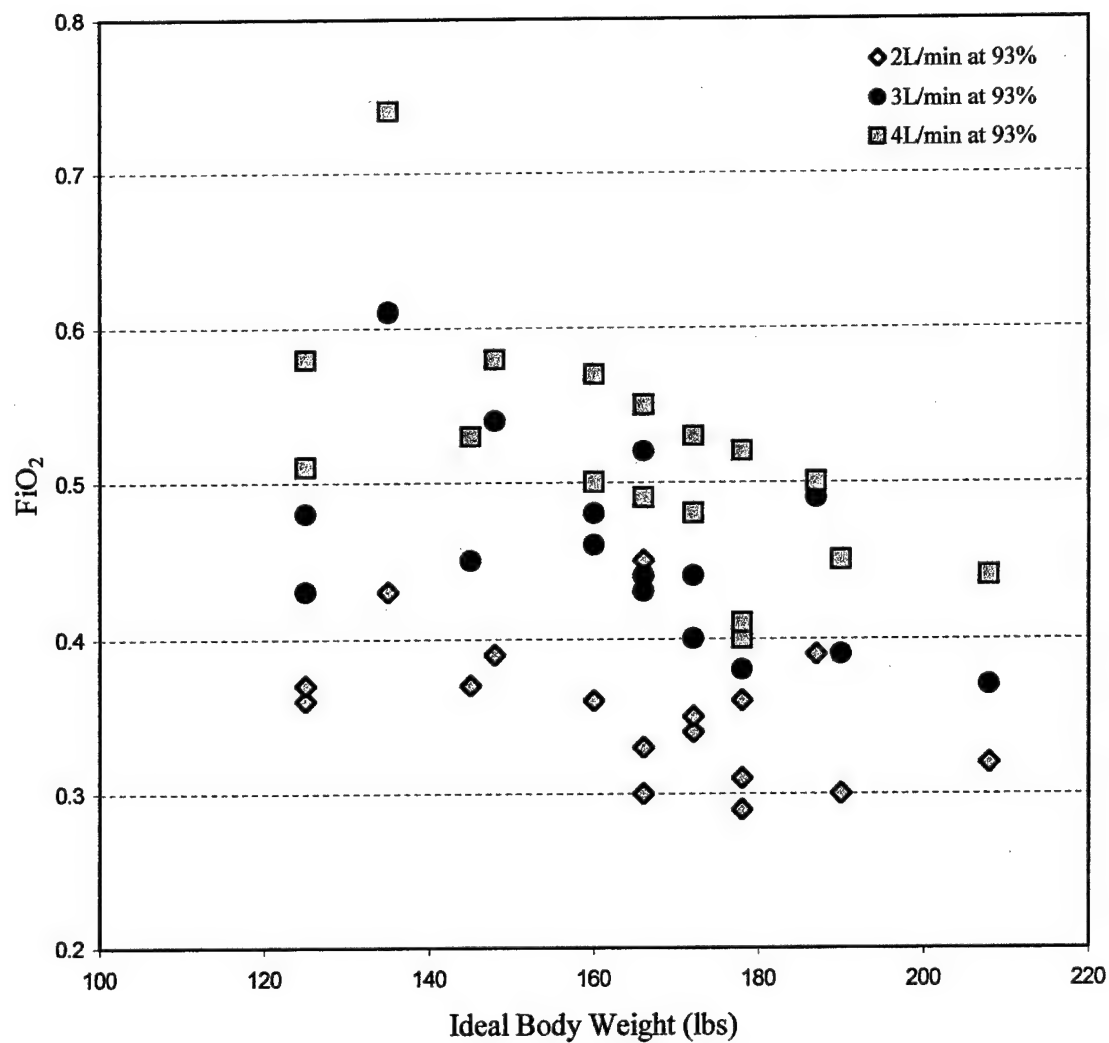


Figure 11. Correlation between FiO_2 and Ideal Body Weight with Oxygen 93% USP

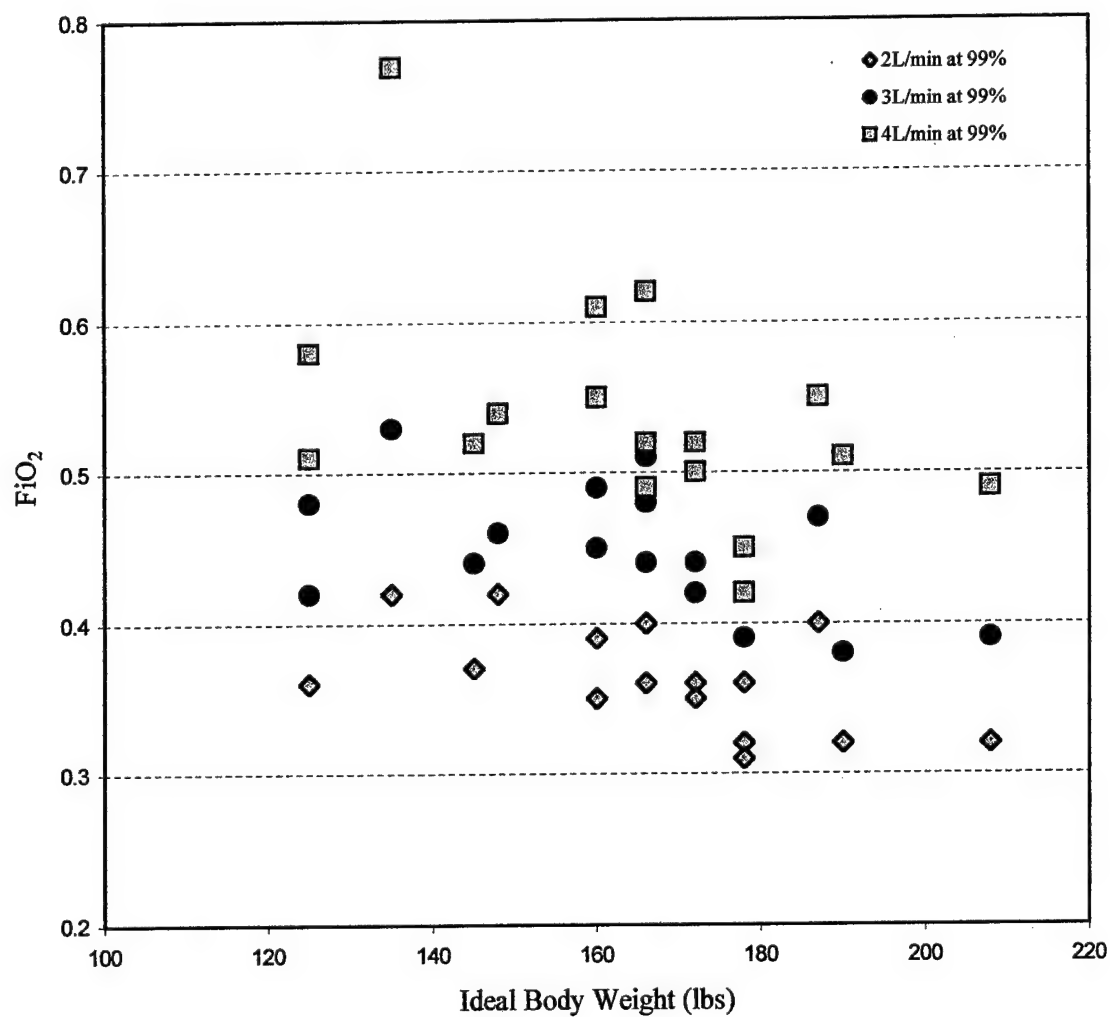


Figure 12. Correlation between FiO_2 and Ideal Body Weight with Oxygen 99% USP

CHAPTER V

Discussion, Conclusions, Implications and Recommendations

The traditional supply of oxygen in large fixed hospitals is supplied from medical gas pipeline systems that rely on liquid oxygen. The medical gas distribution system consists of several pipelines connecting the central supply to areas of the facility where oxygen is needed for patient use. Larger medical facilities have a central supply of oxygen in a separate building outside of the hospital to provide for safe storage of oxygen. Many times liquid oxygen is used in order to store large amounts of oxygen. Liquid oxygen must be stored below its boiling point (-297°F) in insulated containers to prevent evaporation (Dorsch & Dorsch, 1999). Due to the logistics of obtaining and storing liquid oxygen, smaller facilities and mobile medical units in the military require large gas cylinders for oxygen storage and delivery.

Devices that concentrate oxygen from ambient air can provide an alternate source of oxygen. Oxygen concentrators are devices that are capable of separating out oxygen from ambient air thereby producing an oxygen enriched gas source. Oxygen concentrators have been found to provide a safe, reliable and cost effective supply of oxygen (Friesen et al., 1999).

Several oxygen delivery devices are currently used in medical treatment facilities throughout the world. Most of these devices require high flows of oxygen to deliver high oxygen concentrations to the patient. The Mercury[®] tube-valve-mask breathing circuit was developed to replace these high flow systems. The Mercury[®] tube-valve-mask breathing circuit is a semi-open oxygen delivery system consisting of a low resistance fishmouth valve with a corrugated tubing reservoir. The advantage of the device in this

configuration is the ability to deliver higher concentrations of oxygen using low oxygen flows. The combination of using an oxygen concentrator as a low flow oxygen source with the Mercury® tube-valve-mask breathing circuit as the oxygen delivery device will provide a cost effective, logistically sound alternative to the current systems in use today.

The purpose of our study looked at the efficacy of using the Mercury® tube-valve-mask breathing circuit at 2, 3 and 4 L/min flow rates with an oxygen concentrator. This chapter will discuss the results of our research, interpret the data based on the theoretical framework and the literature review, and explore the strengths and weaknesses of the research to include its limitations. Finally, we will discuss conclusions related to the data, implications for anesthesia nursing practice and recommendations for further study.

Discussion

We had three hypotheses for this study. The first hypothesis stated that the Mercury® tube-valve-mask breathing circuit will deliver a FiO_2 of 0.40 when supplied with concentrator gas (Oxygen 93% USP) or Oxygen 99% USP at 2 L/min. The second hypothesis stated that the Mercury® tube-valve-mask breathing circuit will deliver a FiO_2 of 0.50 when supplied with concentrator gas (Oxygen 93% USP) or Oxygen 99% USP at 3 L/min. The third hypothesis stated that the Mercury® tube-valve-mask breathing circuit will deliver a FiO_2 of 0.60 when supplied with concentrator gas (Oxygen 93% USP) or Oxygen 99% USP at 4 L/min. Our criterion for accepting the hypotheses was that 85% of the subjects tested must achieve the desired FiO_2 at the predetermined flow rate. The criterion was not reached in any of the conditions tested as displayed in Tables 4, 6 and 8.

According to Mackie (1987), the major determinants of FiO_2 are oxygen flow, total ventilation and reservoir size. Our theoretical framework states that the FiO_2 varies

directly with the flow rate and inversely with the minute ventilation. We were expecting to see an increase in the FiO_2 delivered to the subject as we increased the flow rate. Consistent with our expectations, we observed an increase in the delivered FiO_2 as we increased the oxygen flow rate (see Figure 2). However, we were unable to achieve the predicted FiO_2 values for our study. In addition, as minute ventilation increased we expected to see a decrease in the FiO_2 . As shown in Table 10, we observed a statistically significant negative correlation between minute ventilation and FiO_2 . The data obtained support the theoretical framework despite failing to obtain our predicted values.

Many different oxygen delivery devices are used to provide for patient needs. The most commonly used devices available include the simple facemask, the venturi mask and the non-rebreathing mask. Our literature review showed that a simple facemask requires flow rates of 6-12 L/min to avoid entrainment of room air. Through this system, oxygen concentrations of 30% - 50% can be achieved. The venturi mask requires flow rates between 3-15 L/min to entrain the requisite volume of room air to obtain oxygen concentrations of 24% - 50%. The non-rebreathing mask requires oxygen flow rates of 10-15 L/min to achieve oxygen concentrations of up to 100%.

Although we did not meet our predicted values of FiO_2 , we did find that the Mercury[®] tube-valve-mask breathing circuit delivered a higher concentration of oxygen at lower flow rates than commonly used oxygen delivery devices currently available. Our data shows that at flow rates of 2-4 L/min we obtained oxygen concentrations of 29% - 74% using the Mercury[®] tube-valve-mask breathing circuit on both sources of oxygen. The mean FiO_2 obtained was 0.35 at 2 L/min, 0.45 at 3 L/min and 0.52 at 4 L/min. This device is roughly equivalent to the venturi mask in oxygen delivery

concentration but requires less than half of the gas flow to obtain these concentrations. This is clinically significant because this device is capable of delivering higher concentrations of oxygen using low flow rates with either an oxygen concentrator or oxygen 99% USP.

The Mercury[®] tube-valve-mask breathing circuit is a new concept. In the review of the literature, there is little information on using low flow oxygen delivery systems to achieve high oxygen concentrations. No studies were found utilizing a low flow oxygen concentrator with an oxygen delivery device to achieve high oxygen concentrations. By conducting this research, we are able to describe the efficacy of the Mercury[®] tube-valve-mask breathing circuit in combination with an oxygen concentrator and provide guidance for future research in this area.

An important consideration is the efficacy of using an oxygen concentrator in the field environment. Oxygen Concentrators are used as the sole source of oxygen in hospitals in Manitoba, Canada. A study of these hospitals found the oxygen concentrators to provide a safe, reliable and cost effective supply of oxygen (Friesen et al, 1999). Libby (1979) has shown that oxygen concentrators tested with a venturi mask set at 24% were capable of delivering oxygen concentrations of 23.7% – 24.9%. We tested all subjects on both Oxygen 93% USP and Oxygen 99% USP. Our findings are consistent with the literature in that graphically we found no difference in the obtained FiO_2 values regardless of the oxygen source used (Figure 2).

The components of minute ventilation are respiratory rate and tidal volume. As a secondary analysis, we looked at the effect of RR and V_t individually on the FiO_2 . We found no statistically significant correlation between the RR and V_t on the FiO_2 .

However, we found a statistically significant inverse correlation between V_e and FiO_2 . The implication is that while we may not be able to use RR or V_t individually to predict the delivered FiO_2 , we may be able to use the minute ventilation. Although statistically this is possible, clinically it may not be beneficial because of the moderate correlations (-0.41 to -0.61) obtained.

Total lung volume depends on the height, weight, age and sex of the individual. Predicted lung volumes are matched to these variables (Levitzky, 1999). Our data looked at correlations between FiO_2 and BMI, IBW and ET_v . One concern of ours was that BMI would have an inverse effect on FiO_2 . However, we found no statistically significant correlation between BMI and FiO_2 . Theoretically, this is supported because BMI is a standardization of height and weight and does not take into account gender or age. Two individuals can be of a different height and weight while mathematically having the same BMI. Therefore, we cannot use BMI as a predictor of FiO_2 .

Our data did show a significant negative correlation between IBW and FiO_2 . IBW differs from BMI in that the IBW takes into account the gender as well as the height of an individual. We also found a significant negative correlation between ET_v and FiO_2 . Again, statistically this would imply that by calculating the IBW and the ET_v we could predict a delivered FiO_2 . However, clinically the correlations for both variables were moderate (-0.46 to -0.64) which may make it difficult to accurately predict the percentage of oxygen that is being delivered to the patient.

Many of the subjects had great variability in the length of time to achieve a sustained FiO_2 in various trial periods. One observation to account for this variability was the issue of sigh breaths or a change in the V_t with regular breathing. A sigh breath

is a random breath with a greater V_t than the normal V_t . Any change in V_t altered the subjects delivered FiO_2 . Subjects with variable times in sustained FiO_2 were noted to have frequent sigh breaths or variable inspired V_t .

Strengths

Strengths of this study include safety for the subject, inter-rater reliability, random assignment, double blinding, consistent atmosphere and repeated measure design. One safety mechanism was an alarm on the concentrator that signified a low oxygen concentration. A light will illuminate if the concentration of oxygen being delivered from the concentrator falls below 85%. A second safety feature is the device itself. The Mercury[®] tube-valve-mask breathing circuit is a semi-open system. Entrainment of room air is possible so that the individual can not receive less than 21% oxygen if there was a loss of the oxygen source. Additionally, all subjects received continuous monitoring of ECG and pulse oximetry.

Inter-rater reliability insured accuracy in the reading of the instrumentation and consistency in the operation of the equipment. All subjects were randomly assigned to increase the internal validity of the study. By double blinding the study, the potential for researcher bias was decreased. The testing investigator as well as the subject did not know which source or flow rate was being delivered. The application of music and dimmed lighting provided a consistent environment and allowed the subject to relax. Finally, in a repeated measures design, the subjects serve as their own control. A repeated measures design is a powerful method of assuring equivalence between the groups being compared. This was done to ensure that any variance the subjects brought to the study was present in all of the trials.

Limitations

The limitations of the study include the use of a convenience sample and the Hawthorne effect. The utilization of a convenience sample limited our ability to generalize the findings to the target population due to a potential selection bias. The Hawthorne effect is the subjects' knowledge of being observed in a study causing a potential change in behavior. Although the subjects were instructed to relax and breathe normally, the Hawthorne effect may have caused them to alter their respiratory rate and depth.

Another limitation of the study included non-continuous sampling of the concentrator output and mask comfort. We did not take into consideration the possibility of variance in the oxygen concentrator output when testing the subjects. Although not measured, mask comfort may have affected the test results. At the conclusion of the trial period, many of the subjects commented on the mask being uncomfortable. Several subjects commented that mask discomfort, claustrophobia and the resistance of the mask to breathing may have possibly altered their respiratory patterns.

Conclusions

We have found that the Mercury® tube-valve-mask breathing circuit is capable of delivering higher concentrations of oxygen using lower flow rates than traditional oxygen delivery systems. Currently, there is no other oxygen delivery system available that can deliver high concentrations of oxygen at these low flow rates. In addition, we were able to achieve these results using an oxygen concentrator. Graphically, we have found there is no difference between the delivered FiO_2 when using either Oxygen 93% USP or Oxygen 99% USP. This supports the usefulness of the combination of the Mercury®

tube-valve-mask breathing circuit and the oxygen concentrator (Oxygen 93% USP) in situations where logistic support for Oxygen 99% USP oxygen is difficult to achieve.

Implications for Nursing

The Mercury[®] tube-valve-mask breathing circuit was designed to deliver high concentrations of oxygen with low gas flows. When used with an oxygen concentrator, the mask is capable of delivering oxygen concentrations higher than traditional oxygen delivery devices. This device is capable of delivering a mean oxygen concentration of 35% at 2L/min, 45% at 3L/min and 52% at 4L/min. In the field environment, use of the Mercury[®] tube-valve-mask breathing circuit is a viable alternative to currently available systems. This combination will assist in conserving the use of a limited resource (oxygen) in the field environment while at the same time providing for higher oxygen concentrations to the patient. The reduction in the use of oxygen coupled with the use of oxygen concentrators will reduce logistical support requirements making mobile medical units in the field more efficient.

Further implications for clinical practice include the findings of our correlations between FiO_2 and IBW, ET_v and V_e . IBW and ET_v were found to be a much better predictor of FiO_2 than BMI, RR or actual V_t . This has important implications for nursing practice in that IBW, ET_v and V_e may be used as a guideline in the prediction of FiO_2 .

Recommendations for Further Research

Recommendations for further research include repeating this study using a larger sample and a random sample. A larger sample size will validate the findings from this study and a random sample would allow the results to be more readily generalized to the

population. We also recommend repeating this study with non-healthy individuals to study the effects that altered metabolic states may have on the delivered FiO_2 .

There have been no studies determining the FiO_2 delivered using the Mercury[®] tube-valve-mask breathing circuit and an oxygen concentrator prior to ours. Due to this, the desired FiO_2 for our study was determined in consultation with Col Steve Janny based on his clinical expertise. Although we did not achieve our desired FiO_2 outcomes of 0.40 on 2L/min, 0.50 on 3L/min or 0.60 on 4L/min, we did find that the Mercury[®] tube-valve-mask breathing circuit delivered higher concentrations of oxygen than traditional low flow oxygen delivery systems. We recommend that the study be repeated using the outcomes we achieved in this study. By setting desired FiO_2 outcomes to 0.35 at 2L/min, 0.45 at 3L/min and 0.50 at 4L/min, the data we collected can be validated statistically and establish that the findings we obtained did not happen by chance.

We received many unsolicited comments about mask comfort and fit at the conclusion of the trials. The discomfort of the mask may have altered the respiratory pattern of the subjects, thus altering the results. We recommend repeating this study with an evaluation of mask comfort and fit. Finally, the maximum output from the Air Sep[®] oxygen concentrator is 6L/min. At 5-6 L/min the concentrator delivers 90% oxygen \pm 3%. We recommend a follow on descriptive study to determine the delivered FiO_2 at these flow rates.

APPENDIX A

Litton® Life Support Flowmeter Correlation Flow Sheet

Litton Life Support Flowmeter Correlation Flow sheet

<u>Flowmeter reading</u>	<u>Liters/min delivered</u>
150	4.652
140	4.357
130	4.063
120	3.749
110	3.445
100	3.141
90	2.807
80	2.493
70	2.179
60	1.844
50	1.510
40	1.186
30	.841
20	.497
10	.152

APPENDIX B

Consent Form

BROOKE ARMY MEDICAL CENTER/WILFORD HALL MEDICAL CENTER**INFORMED CONSENT DOCUMENT****(Revised: 19 Aug 99)****A Descriptive Study of the Percentage of Oxygen Delivered Using the Mercury® Tube-Valve-Mask Breathing Circuit at 2L/min, 3L/min and 4L/min flow rates**

You are being asked to consider participation in this research study. The purpose of this study is to determine the percentage of oxygen you will receive from an oxygen mask manufactured by Mercury Medical Systems. The study will have two sources of oxygen. One source will be from a machine that is able to concentrate oxygen from the air and the other will be from oxygen that is supplied from a medical gas supply company.

This study will enroll 18 subjects at Brooke Army Medical Center/Wilford Hall Medical Center, over a period of 1 day, and will require that you make 1 outpatient visit with Capt Brent Mitchell, Capt Ray Baker, Capt Stephanie Gardner, Capt Aaron Holloway, Capt Alan Todd or Capt Anita Upp during your participation. You have been selected to participate in this study because a healthy individual with no active pulmonary or cardiac diseases.

RANDOMIZATION OF STUDY PARTICIPANTS:

As a participant, you will be randomly assigned to one of 2 treatment plans. Randomization is a process like flipping a coin and means you will have a chance of being assigned to any of the plans.

This study is a double blind study, which means that neither you nor your investigator will know which oxygen source or flow rate you are receiving. In the event of an emergency, there is a way to determine which you are receiving.

PROCEDURES:

As a participant, you will undergo the following procedures: You will be placed in a room and a probe (pulse oximeter) will be placed on your finger. The probe will measure the amount of oxygen in your blood at that point. A mask will be placed on your face and secured with a strap. You will be asked to breathe normally through the mask. Music will be provided to help you relax. You will be breathing oxygen from one of two different sources. One source will be from a machine that is able to concentrate oxygen from the air and the other will be from oxygen that is supplied from a medical gas supply company. The rate of oxygen flow will be adjusted. The flow rate will be randomly assigned. Initially you will receive 2 L/min, 3 L/min or 4 L/min flow, and the investigator will be writing down how much oxygen you are receiving. When the oxygen concentration that you receive levels off, the flow rate will be changed to one of the other flow rates until all three flow rates have been tested. This procedure will then be repeated with the other source of oxygen. You will get a rest period between the trials.

Should it be necessary for you to have a procedure requiring additional informed consent, a separate consent form will be completed at the time of the procedure.

RISKS OR DISCOMFORTS:

There is no known risk associated with this study. If you become pregnant or feel you might be pregnant, contact the study investigator listed in the voluntary participation section. There may also be unforeseen risks associated with this study.

BENEFITS:

There is no guarantee you will receive any benefit from this study other than knowing that the information may help future patients.

PAYMENT (COMPENSATION)

You will not receive any compensation (payment) for participating in this study.

ALTERNATIVE TREATMENT:

Choosing not to participate in this study is your alternative to volunteering for the study.

CONFIDENTIALITY OF RECORDS OF STUDY PARTICIPATION:

Records of your participation in this study may only be disclosed in accordance with federal law, including the Federal Privacy Act, 5 U.S.C. 552a and its implementing regulations. DD Form 2005, Privacy Act Statement-Health Care Records, contains the Privacy Act Statement for the records. By signing this document, you give your permission for information gained from your participation in this study to be published in medical literature, discussed for educational purposes and used generally to further medical science. You will not be personally identified; all information will be presented as anonymous data.

Your records may be reviewed by the U.S. Food & Drug Administration (FDA), other government agencies, the BAMC/WHMC Institutional Review Boards, Mercury Medical Systems and by The University of Texas Health Science Center at Houston, US Army Graduate Program in Anesthesia Nursing.

Complete confidentiality cannot be promised, particularly for military personnel, because information regarding your health may be required to be reported to appropriate medical or command authorities.

ENTITLEMENT TO CARE:

Your entitlement to medical and dental care and/or compensation in the event of injury is governed by federal laws and regulations, and if you have questions about your rights as a research subject or if you believe you have received a research-related injury, you may contact the Brooke Army Medical Center Protocol Coordinators, 210-916-2598 or BAMC Judge Advocate, 210-916-2031.

Participation in this study does not alter your ongoing medical benefits as a military beneficiary, and you will continue to receive any needed medical treatment should you experience illness or injury as a result of this study. In the event of injury resulting from the investigational procedures, the extent of medical care provided is limited and will be within the scope authorized for DOD health care beneficiaries.

STATEMENT OF GOOD FAITH:

The investigator cannot guarantee or promise that you will receive benefits from this study; however, the investigator will keep you informed of any serious complications, which may result from your participation in this study. You will not be informed of results of the tests performed during this study.

VOLUNTARY PARTICIPATION:

The decision to participate in this study is completely voluntary on your part. No one has coerced or intimidated you into participating in this project. You are participating because you want to. The principle investigator, Capt Brent Mitchell, or the associate investigators Capt Ray Baker, Capt Stephanie Gardner, Capt Aaron Holloway, Capt Anita Upp and Capt Larry Todd have adequately answered any and all questions you have about this study, your participation, and the procedures involved. The principal investigator or any associate investigator will be available at (210) 221-6328 to answer any questions concerning procedures throughout this study. If significant new findings develop during the course of this study that may relate to your decision to continue participation, you will be informed.

You may withdraw this consent at any time and discontinue further participation in this study without affecting your eligibility for care or any other benefits to which you are entitled. Should you choose to withdraw, you must notify one of the investigators in the study. The investigator of this study may terminate your participation in this study at any time if he/she feels this to be in your best interest.

The sponsor of this study may terminate the study and/or your participation in this study for safety reasons or if the drug receives FDA approval. There is no guarantee that the device tested during this study will be available through the military system.

Your consent to participate in this study is given on a voluntary basis. All oral and written information and discussions about this study have been in English, a language in which you are fluent.

A copy of this form has been given to you.

VOLUNTEER'S SIGNATURE

_____-_____-_____
VOLUNTEER'S SSN

DATE

VOLUNTEER'S PRINTED NAME

FMP

_____-_____-_____
SPONSOR'S SSN

ADVISING INVESTIGATOR'S SIGNATURE

_____-_____-_____
DATE (PHONE #)

PRINTED NAME OF ADVISING INVESTIGATOR

WITNESS' SIGNATURE
(Must witness ALL signatures)

DATE

PRINTED NAME OF WITNESS

APPENDIX C

Demographic Data and Health History

Demographic Data and Health History

Date _____

Subject # _____

Height _____ inches

Weight _____ pounds

Age _____

Sex _____

Medications: _____

Allergies: _____

Are you allergic to latex? _____

Do you smoke? _____ How much in the last year? _____

Are you pregnant? _____ Is there any possibility of being pregnant? _____

History:

Have you ever had asthma? _____

Have you ever had COPD? _____

Have you had pneumonia in the last 6 months? _____

Have you had bronchitis in the last 6 months? _____

Have you had shortness of breath in the last 6 months? _____

Have you had difficulty breathing in the last 6 months? _____

Have you had a cold or flu in the last 2 weeks? _____

Have you ever had chest pain? _____

Have you ever had a heart attack? _____

Are you seeing a healthcare practitioner for anything? _____

Do you have any other medical history that relates to this study? _____

APPENDIX D
Data Collection Tool

Date		Subject		Base Line		Post Test	
Data Recorder		Age		Temp		HR	
Investigator		Gender		BP		EP	
		Race		RR		ER	
		Height (in)		Sats		Sats	
		Weight (lb)					

Flow Rate		Source		Tidal	Minute	AirSep
Time	FI02	RR	EtCO2	Vol	Vol	Output
30 sec						
60 sec						
90 sec						
120 sec						
150 sec						
180 sec						
210 sec						
240 sec						
270 sec						
300 sec						
330 sec						
360 sec						
390 sec						
420 sec						
450 sec						
480 sec						
510 sec						
540 sec						
570 sec						
600 sec						
630 sec						
660 sec						
690 sec						
720 sec						
750 sec						
780 sec						
810 sec						
840 sec						
870 sec						
900 sec						
930 sec						
960 sec						
990 sec						
1020 sec						
1050 sec						
1080 sec						
1110 sec						
1140 sec						
1170 sec						
1200 sec						
1230 sec						
1260 sec						
1290 sec						
1320 sec						
1350 sec						
1380 sec						
1410 sec						
1440 sec						
1470 sec						
1500 sec						

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VITAE

Raymond Edward Baker was born in Troy, Ohio on February 17, 1965, the son of Lowell Edward Baker and Maida Joy Baker. After completing his work at Metamora High School, Metamora, Illinois, in 1983, he entered Saint Francis College in Fort Wayne, Indiana. He received the degree of Bachelor of Science with a major in Nursing from Saint Francis College in May, 1994. During the following eight years, he was employed as a Nurse in the United States Air Force. In June, 2000, he entered the Graduate School of the University of Texas at Houston. He is currently working toward his Masters of Science in Nurse Anesthesia.

This thesis was typed by Capt Brent E. Mitchell, Capt Raymond Baker, Capt Stephanie M. Gardner, Capt Aaron F. Holloway, Capt Larry A. Todd and Capt Anita S. Upp

VITAE

Stephanie Maria Gardner was born in Minneapolis, Minnesota on June 7, 1965, the daughter of Eddie Lee Battier and Kathryn Ann Williams. Upon completing her work at Robbinsdale Armstrong High School in Plymouth, Minnesota in 1983, she entered the United States Army. After a four-year tour with the Army she entered the University of Minnesota, Twin Cities Campus, Minneapolis, Minnesota. She received a degree of Bachelor of Science with a major in Nursing from the University of Minnesota in June of 1991. During the following eleven years, she was employed as a Registered nurse in the United States Army and Air Force. In June 2000, she entered the U. S. Army Graduate Program in Anesthesia Nursing affiliated with the Graduate School at the University of Texas at Houston Health Science Center. She is currently working toward her Masters of Science in Nurse Anesthesia. In 1997, she married Edgar Lee Gardner Jr. of Goldsboro, North Carolina. Daughter, Jada Danyale Gardner was born in 1998.

This thesis was typed by Capt Brent E. Mitchell, Capt Raymond Baker, Capt Stephanie M. Gardner, Capt Aaron F. Holloway, Capt Larry A. Todd and Capt Anita S. Upp

VITAE

Larry Alan Todd was born in Charleston, South Carolina on July 7, 1970, the son of Clarence Larry Todd and Annette Buchannan Todd. After completing his work at Bishop England High School, Charleston, South Carolina, in 1988, he entered Clemson University School of Nursing in Clemson, South Carolina. He received a Bachelor of Science in Nursing from Clemson University in May, 1993. During the following seven years, he was employed as a nurse in the United States Air Force. In June, 2000, he entered the U.S. Army Graduate Program in Anesthesia Nursing. He is currently working toward his Masters of Science in Nurse Anesthesia. In 1996, he married Karen Louise Kortryk of Rochester, Michigan. Daughters' Natalie Marie Todd was born in July 1997, and Allyson Louise Todd was born in May, 2000.

This thesis was typed by Capt Brent E. Mitchell, Capt Raymond Baker, Capt Stephanie M. Gardner, Capt Aaron F. Holloway, Capt Larry A. Todd and Capt Anita S. Upp

VITAE

Anita Santiago Upp was born in McFarland, California on May 8, 1958. She received the degree of Bachelor of Science with a major in Nursing from California State University at Bakersfield in June 1988. Upon graduating with her degree in Nursing, she became employed at Kern Medical Center Surgical Intensive Care Unit until joining the United States Air Force in June 1997. In June 2000, she entered the Graduate School of the University of Texas at Houston Health Science Center. She is currently working toward her Masters of Science in Nurse Anesthesia. She is married and has three children.

This thesis was typed by Capt Brent E. Mitchell, Capt Raymond Baker, Capt Stephanie M. Gardner, Capt Aaron F. Holloway, Capt Larry A. Todd and Capt Anita S. Upp